

**EVALUATION OF COMMON CAUSATIVE ORAGANISMS OF  
ABNORMAL VAGINAL DISCHARGE AND EFFECTIVENESS  
OF SHORT COURSE INTRAVAGINAL CLOTRIMAZOLE  
AND CLINDAMYCIN THERAPY IN THE SAME**

Dissertation submitted for

**M.D. DEGREE BRANCH II  
[OBSTETRICS AND GYNAECOLOGY]**



**DEPARTMENT OF OBSTETRICS AND GYNAECOLOGY  
THANJAVUR MEDICAL COLLEGE ,  
THANJAVUR.**

**THE TAMILNADU Dr. M.G.R. MEDICAL UNIVERSITY,  
CHENNAI.**

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## **CERTIFICATE**

This is to certify that the dissertation entitled “**EVALUATION OF COMMON CAUSATIVE ORAGANISMS OF ABNORMAL VAGINAL DISCHARGE AND EFFECTIVENESS OF SHORT COURSE INTRAVAGINAL CLOTRIMAZOLE AND CLINDAMYCIN THERAPY IN THE SAME**” submitted for **M.D BRANCH II OBSTETRICS AND GYNAECOLOGY**, The TamilnaduDr.MGR Medical University, Chennai April 2013 is a bonafide work done by**Dr.R.BAVYA**, under my direct supervision and guidance in the **DEPARTMENT OF OBSTETRICS AND GYNAECOLOGY, THANJAVUR MEDICAL COLLEGE, THANJAVUR**during her study period.

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## **DECLARATION**

I Dr.R.Bavya,solemnly declare that the dissertation titled **“EVALUATION OF COMMON CAUSATIVE ORAGANISMS OF ABNORMAL VAGINAL DISCHARGE AND EFFECTIVENESS OF SHORT COURSE INTRAVAGINAL CLOTRIMAZOLE AND CLINDAMYCIN THERAPY IN THE SAME”**is a bonafide work done by me at The Department of Obstetrics & Gynaecology, Thanjavur Medical College,Thanjavur under the guidance and supervision ofmy beloved Prof.Dr.S.Swaruparani,M.D.,D.G.O.,

This is submitted to the TamilnaduDr.M.G.R.Medical University, Chennaiin the partialfulfilment of requirement for the award of M.D.degreeBranch Obstetrics & gynaecology degree examination to be held in April 2013.

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About 10-30% patients treated for BV with oral metronidazole have been shown to develop candidiasis later. Less common side effects include dizziness, peripheral neuropathy and convulsions as the drug crosses the blood brain barrier. These unpleasant side effects and longer duration of treatment (7-14days) are major factors responsible for non-compliance to treatment. Also to be remembered are the risks of change in normal commensal vaginal flora and the possibility of emergence of antibiotic resistance.<sup>2,3</sup>Hence our study evaluated an alternate therapeutic regime not involving oral metronidazole and employing a shorter duration of treatment.

Using simple microscopic assessment by <sup>32</sup>Gram's stain of the vaginal smear is emerging as a sensitive non- cultural diagnostic technique for bacterial vaginosis <sup>4,5</sup> and candidiasis <sup>5</sup>. Direct microscopy (wet mount) of the vaginal discharge showing motile Trichomonas vaginalis has been demonstrated to be as accurate (in terms of specificity) as culture for diagnosing Trichomoniasis.

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TABLE OF CONTENTS S.NO TITLE PAGE NO 1 Introduction 1 2 Aim of study 3 3 Review of Literature 4 4 Materials and Methods 2 5 Observation 24 6 Discussion 27 7 Summary 74 8 Conclusion 76 9 Bibliography 10 Proforma 11 Master chart INTRODUCTION Vaginal discharge is a common gynaecological symptom affecting many women. It is a source of considerable discomfort, worry and self- treatment. Consultation is often delayed due to embarrassment or fear as many women believe sexual transmission plays the main role in causing gynaecological symptoms and anything related to sexual transmission is still taboo in developing countries like ours. The treatment of vaginal and cervical infections is quite...

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## **ABBREVIATION**

WHO	–	World Health Organization
BV	–	Bacterial Vaginosis
TV	–	Trichomonas Vaginalis
VVC	–	Vulvo Vaginal Candidiasis
CDC	–	Centre for Disease Control
RCT	–	Randomized Control Trials
AIDS	–	Acquired Immuno Deficiency Syndrome
KOH	–	Pottasium Hydroxide
mg	-	milligram

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## ABSTRACT

**AIM:** To evaluate the common causes of abnormal vaginal discharge among women of reproductive age group attending a tertiary care hospital using simple laboratory techniques and to study the effectiveness of short course intravaginal therapy in treating the same. **MATERIALS AND METHODS:** High vaginal swabs were taken from 200 women complaining of abnormal vaginal discharge. Bacterial vaginosis was diagnosed by gram stain using Nugent's criteria, candidiasis by gram stain showing budding yeast cells and pseudohyphae, trichomoniasis by wet mount showing motility of trophozoites. Women in whom the cause was found were treated with clotrimazole alone for TV and candidiasis, clotrimazole and clindamycin (vaginal suppositories for three consecutive nights) for those having BV alone or along with the other two conditions. **RESULTS:** Above mentioned simple laboratory techniques identified the cause of abnormal vaginal discharge in 74% patients. Most common cause (alone or along with other two causes) was BV in 60% cases, candidiasis in 16.5% cases, TV in 10% cases. There was significant association between the symptoms, nature, odour, pH of the vaginal discharge and the causative organism. The treatment given cured 82.5% cases having BV, 81.8% cases having candidiasis and 40% cases having trichomoniasis. **CONCLUSION:** Correlating symptomatology with simple laboratory techniques helps to arrive at a more accurate diagnosis of abnormal vaginal discharge. Short course intravaginal therapy is safe and effective in treating abnormal vaginal discharge due to BV and candidiasis but not very effective in trichomoniasis. **KEYWORDS:** "Bacterial vaginosis", "candidiasis", "trichomoniasis", "short course", "intravaginal therapy", "clotrimazole", "clindamycin".

## INTRODUCTION

Vaginal discharge is a common gynaecological symptom affecting many women. It is a source of considerable discomfort, worry and self-treatment. Consultation is often delayed due to embarrassment or fear as many women believe sexual transmission plays the main role in causing gynaecological symptoms and anything related to sexual transmission is still taboo in developing countries like ours.

The treatment of vaginal and cervical infections is quite difficult in developing countries as there is scarcity of laboratory facilities for identifying these infections. WHO promoted the syndromic-based management for this reason.<sup>1</sup>

WHO syndromic approach is centered on identifying a relatively constant group of signs and symptoms (syndrome) and on the awareness of the most common organisms causing these conditions and their susceptibility to various drugs. Drug regimens were selected to cover the major pathogens accountable. The main shortcoming of this approach is the use of oral metronidazole in most regimes. Oral metronidazole is associated with nausea, vomiting, anorexia in many patients.

About 10-30% patients treated for BV with oral metronidazole have been shown to develop candidiasis later. Less common side effects include dizziness, peripheral neuropathy and convulsions as the drug crosses the blood brain barrier. These unpleasant side effects and longer duration of treatment (7-14days) are major factors responsible for non-compliance to treatment. Also to be remembered are the risks of change in normal commensal vaginal flora and the possibility of emergence of antibiotic resistance.<sup>2, 3</sup> Hence our study evaluated an alternate therapeutic regime not involving oral metronidazole and employing a shorter duration of treatment.

Using simple microscopic assessment by Gram's stain of the vaginal smear is emerging as a sensitive non- cultural diagnostic technique for bacterial vaginosis <sup>4, 5</sup> and candidiasis <sup>5</sup>. Direct microscopy (wet mount) of the vaginal discharge showing motile *Trichomonas vaginalis* has been demonstrated to be as accurate (in terms of specificity) as culture for diagnosing Trichomoniasis.

## **AIM OF THE STUDY**

1. To study the prevalence of Bacterial vaginosis, candidiasis and Trichomoniasis in patients complaining of abnormal vaginal discharge in the reproductive age group using simple laboratory techniques.
2. To study the efficacy of short course (3 days) intra-vaginal Clindamycin and Clotrimazole therapy in treating the above said 3 conditions.

## **REVIEW OF LITERATURE**

### **BACTERIAL VAGINOSIS**

Bacterial vaginosis (BV) is a polymicrobial syndrome caused by an imbalance of the commensal vaginal organisms resulting from the replacement of high levels of hydrogen peroxide producing *Lactobacillus* species by non-dominant or exogenous bacteria (GIRALDO et al 2007, SCHWEBKE 2009)□. Along with unpleasant vulvovaginal symptoms and a rise in the vaginal pH (usually  $\geq 4.5$ ), BV is linked with augmented risks of other complications like pelvic inflammatory disease (PID), pregnancy associated complications like preterm labour and postoperative infections. In affected women belonging to the high risk group, there is also increased likelihood of acquiring HIV<sup>6,7</sup>.

The ecologic dynamics linked to the vaginal microorganisms shift in patients affected by BV has not been fully deciphered. It is supposed that with a small number of exceptions, BV associated microbial organisms exist in low concentrations in the vaginal flora of normal healthy women (FORSUM et al., 2005).

### **SYMPTOMATOLOGY:**

Many women suffering with BV are asymptomatic. The most common symptom in affected women is a homogenous creamy discharge, associated with an offensive odour. Risk factors for BV include African-American race, several sex partners, women having sex with women and vaginal douching<sup>8</sup>. Hormone contraceptive pill use, male circumcision and use of condoms decrease BV incidence. Though related with earlier age of first sexual intercourse and numerous sexual partners, BV is not included under sexually transmitted diseases<sup>8</sup>.

**Diagnosis:** There is no gold standard test described for BV. In as much as half of women who are asymptomatic, cultures show organisms like *Gardnerellavaginalis*. Amsel's criteria are time and again employed as reference standard for evaluating symptomatic women, the best aspirant for a gold standard diagnostic test is in all probability Gram stain evaluation by means of Nugent's criteria.<sup>9</sup>

<b>Nugent's Gram stain criteria Lactobacillus morphophytes(large gram +ve rods)</b>	<b>Gardnerella and Bacteroides species Morphophytes (small gram – ve rods )</b>	<b>Mobiluncus species (Curved gram-variable rods)</b>	<b>Points</b>
4+	0	0	0
3+	1+	1+ or 2+	1
2+	2+	3+ or 4+	2
1+	3+		3
0	4+		4
Points are awarded to the first 3 columns based on microscopic examination.			
<p>To get a final sum, points for all 3 columns are added.</p> <p>Score 0-3: negative for BV</p> <p>4-6 : intermediate</p> <p>7-10 : diagnostic for BV</p> <p>Source: Nugent et al 1991.<sup>9</sup></p>			

Gram stain is more unbiased and reproducible by different observers compared to wet mount microscopy, having specificity of 70% and sensitivity of 93%.<sup>10</sup>

Criteria to be employed in research studies for defining normal vaginal microbiota and BV as proposed by the International Working Group on Bacterial Vaginosis<sup>11</sup>:\* BV is considered present if Nugent score is  $\geq 7$  or when modified Amsel criteria are significantly positive, without regard to symptoms. When symptoms are present they must be separately recorded. Abnormal symptoms must include, as a minimum, patient's complaint of an increased, foul smelling vaginal discharge.

\* Vaginal microflora is considered to be a normal one if *Lactobacillus* is the principal species, in which case, Nugent score is  $< 4$ .

#### Definition of cure of BV<sup>11</sup>

Different studies on BV have employed diverse agendas to define outcomes of therapy. The Working group was of the general consensus that though some classical features of BV recover very fast with therapy (like loss of plenty of clue cells), other features take significantly longer time (like vaginal pH normalization). Preferably, the evaluation should be taken up after 7 - 10 days of initiation of treatment, and would help to estimate the cure rate (early



treatment efficacy). At this evaluation, cure must be defined as lack of substantial number of clue cells (<20% of the epithelial cells on wet mount microscopy at 100× magnification) or **achievement of Nugent score of  $\leq 6$** ; Improvement of symptoms must be included, but that would comprise a discrete component of therapeutic response.

## **TREATMENT OPTIONS:**

### **Metronidazole:**

Metronidazole is a antimicrobial drug belonging to the nitroimidazole group, used in management of protozoal infections like trichomoniasis as well as in anaerobic infections.<sup>12</sup> Metronidazole is being widely used in the treating BV with good therapeutic results .<sup>12</sup> Numerous preparations allowing oral or vaginal administration and various regimens have been under study. Treatment with metronidazole is complicated by side effects which include gastrointestinal symptoms (nausea, vomiting, metallic taste in the mouth) and development of candidiasis. Such side effects are being used to substantiate single-dose oral metronidazole therapy or topical metronidazole.

They are also accountable for problems in following a 7 day course of treatment and subsequently end up in treatment failure. Inadequate cure will be

complicated by an augmented risk of disease recurrence and development of resistance to metronidazole.<sup>13</sup>

## **Clindamycin**

Clindamycin is the next common antimicrobial used for treating BV. It is a lincosamide antibiotic, belonging to a larger family of macrolide antibiotics. Clindamycin is available in various treatment forms including oral and vaginal (ovule and cream). A study by Mikamo et al.<sup>14</sup> evaluated the oral clindamycin vs. intra-vaginal application in treatment of BV. In this study, 450 mg clindamycin administered orally thrice a day and 2% clindamycin as vaginal cream 5 g once a day, both for a 7 day period, had parallel cure rates. A randomized study by Sobel et al.<sup>15</sup> compared the efficacy of clindamycin vaginal cream (5 g at bedtime for 7 days) with clindamycin vaginal ovules (100 mg daily for 3 days) for treating BV. The cure rates were similar.

## **Clindamycin vs. metronidazole**

According to the CDC BV working group, oral clindamycin (500 mg twice daily for 7 days) or topical clindamycin (ovule 100 mg once a day for 3 days ; 2% clindamycin cream 5 g once daily for 7 days) appeared to be equally

effective to oral (500 mg two times a day for 7 days) or topical metronidazole (0.75% gel 5 g once a day for 7 days).<sup>16</sup> Moreover, it was noted that topical clindamycin was more likely to produce lesser adverse effects (nausea, vomiting, metallic taste in the mouth) compared to oral metronidazole.<sup>8</sup>

A Cochrane review<sup>16</sup> of 24 RCTs (randomized controlled trials) in 2009 concluded that both metronidazole and clindamycin were equally effective, after two to three weeks of treatment, achieving proven cure in 92 and 91 percent of patients, respectively. 6 RCTs showed oral and topical antibiotics were equally active in achieving cure. The main drawback of oral regimens is that a longer period of treatment. Intra-vaginal clindamycin cream is preferable in cases of intolerance or allergy to metronidazole. Metronidazole 2g single dose has the least efficacy for curing bacterial vaginosis and is no longer used or recommended.

According to a study by Jorma Paavonen et al<sup>17</sup>, a 3 day treatment course of transvaginal ovules of clindamycin, was as efficacious as and better tolerated than a 7 day course of oral metronidazole 500mg BD, for treating bacterial vaginosis.

**Newer drug delivery systems:**

Vaginal routes of administration of metronidazole or clindamycin is a commonly practised method in the treatment of BV, but their efficacy is questionable. Several works have been done so as to improve existing preparations or producing new drug delivery systems. A study in Egypt has established a hydrogel that swells up in aqueous surroundings for potential use as a drug delivery vehicle. This new vaginal drug delivery system for metronidazole, has been shown to improve the therapeutic effectiveness as compared to that accomplished with the traditional vaginal gel.<sup>18</sup>

In addition, new bioadhesive film preparations of clindamycin for vaginal administration have been formulated<sup>19</sup>. The antibacterial activity and properties of these new preparations in vitro may offer a welcome change to conventional dosage formulations for topical vaginal application.

The triumph of such novel dosage formulations and bio-adhesive productions structured to extend the dwelling time of the drug in the vagina is yet to be evaluated.

### **Effect of antifungal therapy on BV:**

Self medication with antifungals is a common practice and it may be beneficial in women with Candida who are also infected with BV. There is a common opinion is that opposing vaginal pH are needed for growth of BV and

*C. albicans*, but this notion is incorrect as combined infections with BV and candida are seen often. Donders et al<sup>20</sup> reported that 9 among the 142 women (about 6%) with symptomatic candidiasis had concurrent BV. Antifungal therapy cured BV in about 70% of women who had simultaneous vulvovaginal candidiasis. Also reported was the fact that though antifungal therapy may be useful in women with coexisting BV, it does not prevent BV occurrence in women without BV. A similar advantage of antifungal treatment has been described in a trial by Sanchez S et al<sup>21</sup> in which women receiving ovules having both nystatin and metronidazole for BV had superior cure rates at 2 weeks after therapy compared to those who received metronidazole 0.75% gel alone (20% & 4%, respectively). Also reported was that the benefits of combination therapy persisted 3 months after completion of treatment (52% and 33%, respectively).

### **Regimens for the treatment of BV according to the US Centre for Disease Control<sup>22</sup>**

Three recommended regimens

1. Metronidazole 500 mg oral two times a day \* 7 days
2. Metronidazole gel 0.75%, 1 application (5 g) intra-vaginally, once a day\*  
5 days
3. Clindamycin cream 2%, 1 application (5 g) intra-vaginally at bedtime \* 7

days

#### Three alternative regimens

1. Tinidazole 2 g oral OD \* 2 days or 1 g oral OD \* 5 days
2. Clindamycin 300 mg oral BD \* 7 days
3. Clindamycin ovules 100mg intra-vaginally once a day \* 3 days

#### Three recommended regimens for pregnant women

1. Metronidazole 500 mg oral BD\* 7 days
2. Metronidazole 250 mg oral TDS\* 7 days
3. Clindamycin 300 mg oral BD \* 7 days

It has been observed from various studies that about 80% of patients treated for BV will have a recurrence within one year of treatment. BV can occur and remit spontaneously. There is no general agreement on the causes of recurrence of BV, and this may explain why some women, even while on adequate therapy, do not respond favourably to drugs effective against anaerobic bacteria. (GIARLDO et al 2007). The proposed causes include, hygiene habits, number of sexual partners, IUCDs, vaginal douches, spermicides, broad spectrum antibiotics, frequent sexual intercourse, deficiency of vaginal immune response,

contamination of lactobacilli with bacteriophages, and the consequent death of protective microorganisms (UGWUMADU; TAYLOR- ROBINSON 1997).

Regular testing & treatment of sex partners is not required. Treating male companions does not decrease relapse rates.<sup>23</sup>

## **VULVOVAGINAL CANDIDIASIS**

Candidiasis is the next commonly diagnosed cause of vaginitis after BV. Studies show that about 75% of womenfolk will have a candida infection at some point of their life and 5% will have repeated episodes.<sup>24</sup> Also observed is the fact that 10% to 30% of women having no symptoms and with normal vaginal flora have positive culture reports for Candida.<sup>25-29</sup> On the other hand, the percentage of symptomatic women who have positive culture reports is 20% to 40%<sup>30,31</sup> Complications due to VVC are infrequent, but few reports on vulvar vestibulitis<sup>33</sup> and chorioamnionitis during pregnancy<sup>32</sup> require special mention.

**Risk factors:** Symptomatic VVC is linked to use of condoms and diaphragms, contemporary antibiotic therapy, receptive oral sex, use of oral contraceptive pills, spermicides, diabetes mellitus and immunosuppressed states including AIDS<sup>31, 34-37</sup>. Though pregnancy is proposed as a risk factor

for VVC, the prevalence of candida on cultures in pregnant women is analogous to that of the non-pregnant population.<sup>30</sup>

**Symptomatology:** In women with culture results positive for Candida, the most common presenting symptom is pruritus or burning sensation in vulva.<sup>28</sup> Abnormal vaginal discharge is reported by majority of women with symptomatic VVC. Women may also report a thick, odourless, cottage cheese-like discharge.<sup>38</sup> A thick, curdy vaginal discharge mostly points to a diagnosis of Candida as it is rarely seen with trichomoniasis or BV .

A study by Eckert LO et al<sup>28</sup> concluded that a thick curdy discharge had an affirmative predictive value of 84% for diagnosing VVC by culture. On the other hand, a thin discharge does not necessarily exclude VVC. On clinical examination, vulva and vagina are often erythematous but these findings are not specific for VVC. A normal vaginal pH of <4.5 is seen in most cases. According to Reed et al<sup>30</sup>, the accuracy of the clinical examination for VVC is quite less in comparison with microscopy and culture.

**Pathogens:** Candida albicans is the most common reported pathogen in 80% to 90% of cases with VVC<sup>39</sup>. Others have non-albicans species, like C glabrata.<sup>28</sup> Horowitz BJ et al and Spinillo A et al<sup>40</sup> reported that an increase in the non-Candida species to almost 20% in a particular study by the mid-



1990's may be due to an augmented use of imidazole that are available easily over-the-counter. In cases of non-Candida VVC, wet mount results are classically negative.<sup>28</sup>

### **Diagnosis of VVC**

- 1) Direct examination: KOH wet mount or Normal saline preparation
- 2) Gram Stain: Identification of yeast cells & pseudo hyphae – yeast cells are about 4-8 microns. Presence of pseudo hyphae indicates colonisation & tissue invasion, hence their demonstration in direct smear of tissue is highly significant.
- 3) Culture: In Sabouraud Dextrose Agar – gold standard: though it indicates colonisation, it does not necessarily indicate infection.

Sensitivity of various diagnostic tests<sup>41</sup>:

Wet mount : 50-60%

Wet mount with KOH: 70-80%

Gram stain : 60-70%

Culture : 30-50%

Treatment<sup>42</sup>:

### **General advice**

- Avoiding local irritants e.g. perfumed products

- Avoiding tight fitting synthetic inner clothing

### **Antifungal drugs:**

All oral and topical azole therapies give 80-95% clinical and microbiological cure in acute vulvo-vaginal candidiasis in the non-pregnant population. Though Nystatin formulations give a 70-90% cure rate, they are not routinely used as typically, a 14 day course is needed.

### **Oral regimens:**

- Flucanazole 150mg stat single dose
- Itraconazole 200mg BD \* 1 day

### **Intra-vaginal regimes:**

- Clotrimazole vaginal pessary: 500mg one dose/100mg OD\* 7 days/  
200mg OD\*3days
- Miconazole vaginal ovule : 1200mg single dose/ 400mg OD \* 3 days
- Econazole vaginal pessary : 150mg single dose

### **CDC Recommended Regimes for uncomplicated Vulvovaginal Candidiasis**

<sup>43</sup>:

- Butoconazole 2% cream

5 g intra-vaginally OD \* 3 days

- Butoconazole 2% sustained release cream

5 g intra-vaginally single dose

- Clotrimazole 1% cream

5 g intra-vaginally OD \*7-14 days

- Clotrimazole 2% cream

5 g intra-vaginally OD \* 3 days

- Miconazole 2% cream

5 g intra-vaginally OD \* 7 days

Thomas B. Lebherz, Larry C. Ford et al<sup>44</sup> in their study comparing 3 day therapy with 200mg clotrimazole pessaries and 7 day therapy with 100mg clotrimazole pessaries found no significant difference in outcome amongst the two groups and concluded that short course treatment is more effective and can be expected to offer better cure as patient compliance is mainly a function of duration of treatment.

Treatment failure is very rare in VVC. Likely causes include poor treatment compliance, wrong diagnosis of initial condition, resistance of organisms to conventional treatment, mixed infection, continuous persistence of an irritant, recurrence of infection and uncorrected underlying problems (diabetes, immunosuppression, concurrent antibiotic use).

## **TRICHOMANAS VAGINITIS:**

Trichomonas vaginalis is the protozoan parasite responsible for Trichomonas vaginitis. It is a common sexually transmitted disease.

Non sexual transmission may occur rarely, through dirty towels or contaminated water.

The prevalence rate in India is about 6-10%<sup>45</sup>. Clinical manifestations range from asymptomatic to acute signs & symptoms like yellowish green, malodorous, often frothy, thin discharge often associated with vulval itching, burning & dysuria. Punctate haemorrhages in cervix “strawberry cervix” though considered to be pathognomonic of trichomoniasis, is present in only 2% of cases.<sup>46</sup>

## **Complications:**

Complications of TV include: preterm delivery ( which in turn leads to low birth weight and an increase in perinatal mortality) as well as predisposition to HIV infection, AIDS, other sexually transmitted diseases and cervical cancer.<sup>47</sup>

Infection with TV has also been described in fallopian tubes, urinary tract and pelvis. TV can cause oral lesions, bronchitis, and pneumonia. Condoms are effective at decreasing, but not fully averting transmission. Recent studies propose a relationship between TV infection in males and subsequent aggressive prostate cancer.

### **Diagnosis:**

- Wet Mount : Simple office diagnostic procedure – demonstrates jerky motility of *Trichomonas vaginalis* trophozoites : 50-80% sensitivity, 100% specificity
- Culture : 75-95% sensitivity – Gold Standard
- Newer methods: rapid antigen testing, PCR and transcription-mediated amplification – more sensitivity but very costly, not routinely used.

In a study by Huppert et al<sup>48</sup>, the sensitivities of wet-mount examination, microbiologic culture, rapid antigen detection tests, and nucleic acid amplification tests were 51%, 75%, 82%, and 98%, respectively. Specificity was close to 100 percent for each method

## **Treatment<sup>43</sup> :**

### **CDC Recommended regimen :**

Metronidazole

2 g oral single dose

Imidazole

2 g oral single dose

### **Alternative regimen**

Metronidazole

500 mg oral BD \*7 days

### **Pregnancy**

Metronidazole

2 g oral single dose

Sexual partners must be treated concurrently. To reduce recurrence, partners must avoid resuming sexual intercourse till both have concluded treatment and are both asymptomatic.

Clotrimazole has a fungicidal action on dermatophytes, yeasts, and other fungi. It also has action on *Trichomonas vaginalis* and clotrimazole-sensitive bacteria.

In a multicentre comparison by duBouchet L et al<sup>49</sup> of clotrimazole vaginal tablets, oral metronidazole, and vaginal pessaries containing sulfanilamide, aminacrine hydrochloride, and allantoin for treating

symptomatic trichomoniasis, it was seen that though oral metronidazole was more effective in eradicating TV, reduction of symptoms was seen in all three study groups and no side effects were observed in the clotrimazole group as compared to the other two groups. It was proposed that Clotrimazole vaginal tablets may prove to be an effective alternative to metronidazole in women who do not tolerate the unpleasant side effects of metronidazole therapy or in whom metronidazole is contraindicated (e.g. First trimester of pregnancy)

## **MATERIALS & METHODS**

This study was conducted in the Department of Obstetrics and Gynaecology, Raja Mirasudar Hospital, Thanjavur Medical College, Thanjavur.

- 200 married, sexually active women in the reproductive age group (15-45years) attending the gynaecology outpatient department complaining of abnormal vaginal discharge were included in the study. Vaginal discharge was classified as abnormal if patients referred to it as the main reason for attending the clinic. Informed consent was taken from all patients.
- Patients with bleeding per vaginum, pregnancy, postpartum, post-menopausal, post-hysterectomy status, those with known genital tract malignancies, those who had taken topical/ oral antifungals/ antimicrobials in the past one month were excluded from the study.
- A detailed history was taken with special reference to the duration, nature, odour of the vaginal discharge and associated vulval itching, lower abdominal pain, dysuria and dyspareunia. History of diabetes, prolonged antibiotic use, oral contraceptive use, any symptoms in husband were also noted.
- A speculum examination was performed on each patient, the nature & colour of the discharge were noted. pH was measured with the help of



narrow range pH paper held with forceps and dipped in vaginal discharge, taking care to avoid cervical secretions.

- Two high vaginal swabs were taken from each patient using sterile cotton wool vaginal swabs by rubbing and rotating in the posterior vaginal fornix. One swab was used immediately to prepare a wet mount by adding one or two drops of normal saline on a glass slide and light microscopy was used to observe the jerky or darting motility of *Trichomonas vaginalis*.
- The other swab was sent to the microbiology lab for gram staining and reporting.
- The diagnostic criteria used for microbiological diagnosis were:
  - 1) Bacterial vaginosis – A Gram's stain score of  $>7$  based on the scoring system by Nugent et al.
  - 2) Candidiasis – if gram positive budding yeasts & pseudo hyphae were seen on gram's stain.
  - 3) Trichomoniasis – if wet smear microscopy was positive for motile *Trichomonas vaginalis*.
- The patients diagnosed to have BV alone or in combination with TV or candidiasis, were given vaginal suppositories containing a combination of Clindamycin 100mg & Clotrimazole 200mg, 3 doses, to be inserted as

high as possible in the vagina, preferably before retiring to bed on three consecutive nights.

- The patients diagnosed to have TV alone or candidiasis alone, were given vaginal suppositories containing only Clotrimazole 200mg, 3 doses, to be inserted as high as possible in the vagina, preferably before retiring to bed on three consecutive nights.
- Those in whom no diagnosis was made were given placebo medications.
- Those patients who received antifungal/antimicrobial treatment or a combination of both were advised to come for follow up, 7-10days after completion of therapy.
- On the follow up visit, a detailed history taking was done with special reference to the symptomatic improvement and any side effects observed during treatment.
- In those patients who were diagnosed to have TV before treatment, wet mount examination was done, and in those earlier diagnosed to have BV or candidiasis, gram stain was repeated.

## **OBSERVATION AND RESULTS**

This study was conducted on 200 women presenting with abnormal vaginal discharge and the following observations were made.

Among the 200 women, one or more causes of the abnormal vaginal discharge were identified in 148 patients. In the remaining 52 patients, no diagnosis could be arrived at, using the above defined diagnostic criteria.

Total number of cases	200	%
Cause identified	148	74%
Cause not identified	52	26%

Table 1

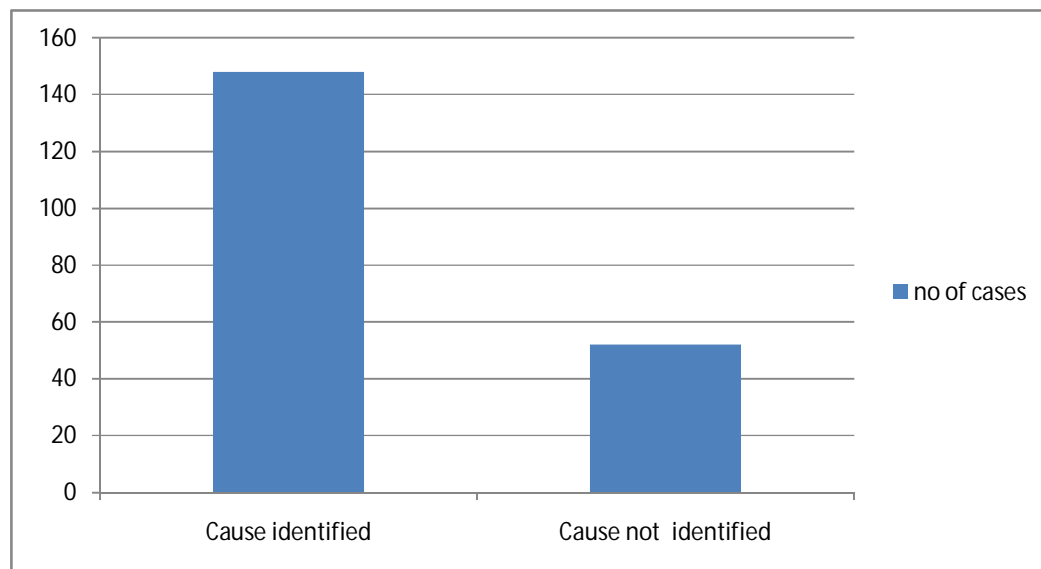


Figure 1

Possible reasons for not identifying cause in 52 cases:

- Physiological vaginal discharge
- Cervical infections like Chlamydia, Gonococcus
- Allergic reactions
- Viral vaginitis

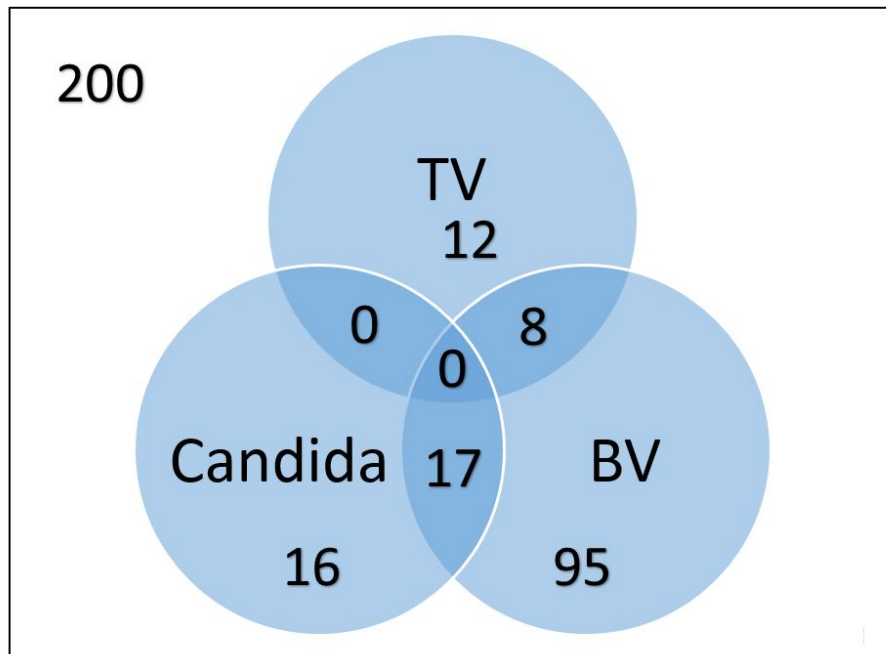
- Inability of the simple laboratory techniques used in the study to accurately identify all cases.

Among the 148 cases in which the cause was identified, bacterial vaginosis (BV) alone or along with the other 2 conditions, was seen in 120 patients (60%); Trichomonas vaginitis (TV) alone or along with BV was seen in 20 patients (10%); and candidiasis alone or with BV was seen in 33 patients (16.5%).

<b>Cause</b>	<b>No of cases</b>	<b>Percentage</b>
BV alone	95	47.5%
Candidiasis alone	16	8%
TV alone	12	6%
BV & candidiasis	17	8.5%
BV & TV	8	4%
No cause identified	52	26%
Total	200	100%

Table 2

## Distribution of Diseases



**Figure 2**

### AGE DISTRIBUTION

The age distribution of patients in our study is as follows:

Age group	No. of cases	Percentage
20-25years	14	7%
25-30 years	58	29%
30-35 years	44	22%
35-40 years	64	32%
40-45 years	20	10%

Table 3

The most common age group of patients in our study was 35-40years (32%)

The mean age of patients was 32.25years.

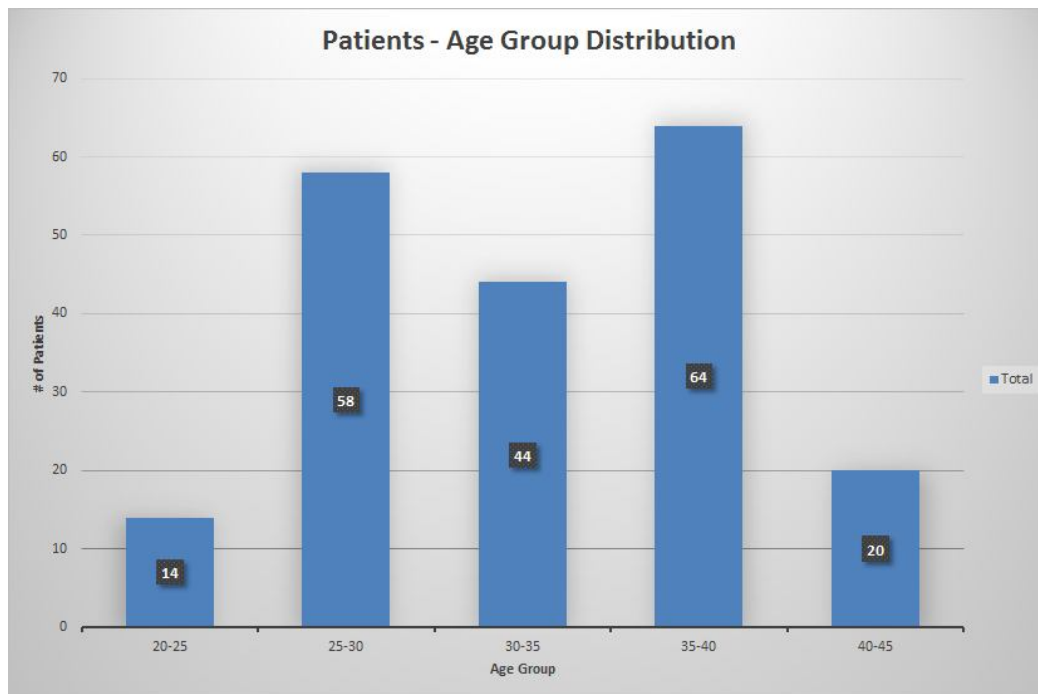


Figure 3

## **SIGNIFICANT ASSOCIATED SYMPTOMATOLOGY:**

### **PRURITUS VULVA**

61 of the 200 women (30.5%) included in our study complained of pruritus vulva. This was the most common presenting complaint next to abnormal vaginal discharge. Other symptoms as told by the patients included lower abdominal pain in 24, dysuria in 16, and dyspareunia in 7 cases.

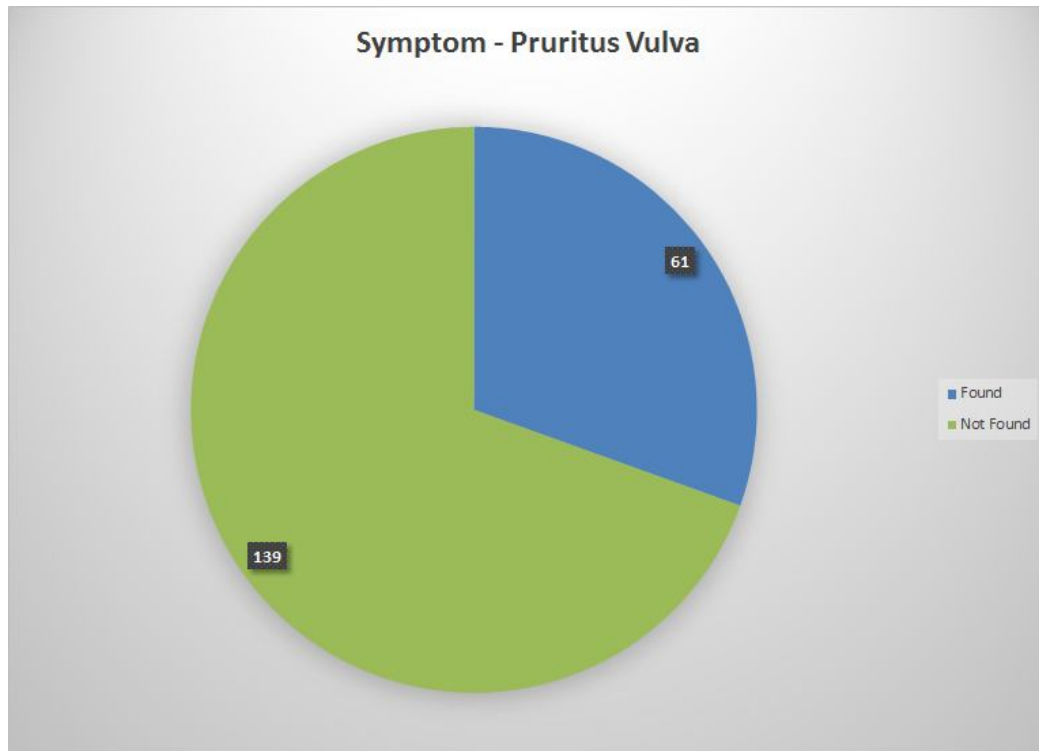


Figure 4



### ODOUR OF THE DISCHARGE:

Of the 200 women included in our study, 112 patients (56%) reported that their vaginal discharge was malodourous while the remaining 88 (44%) said that there was no odour associated with their vaginal discharge.

Odour of discharge	No. of cases	Percentage
Malodour	112	56%
No odour	88	44%

Table 4

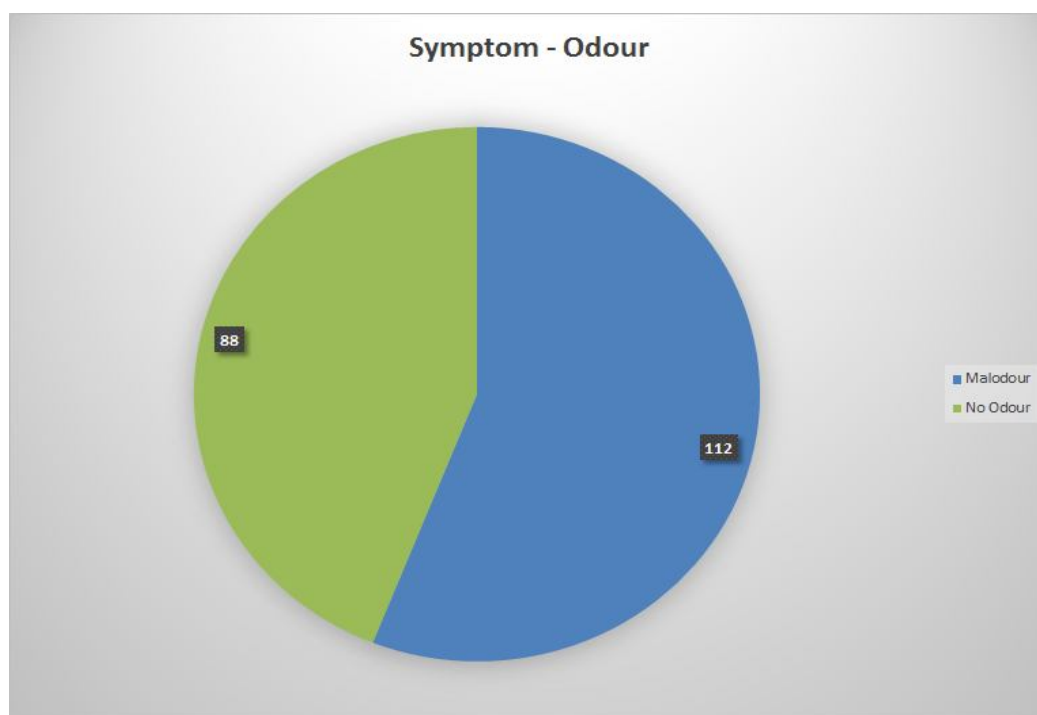


Figure 5

### COLOUR & NATURE OF THE VAGINAL DISCHARGE:

All 200 women included in our study were subjected to speculum examination and the colour and nature of the discharge as noted by the clinician were classified as homogenous creamy in 139 patients(69.5%), curdy white in 32 patients(16%), frothy green in 29 patients(14.5%).

Nature of discharge	No. of cases	Percentage
Homogenous creamy	139	69.5%
Curdy white	32	16%
Frothy green	29	14.5%

Table 5

Homogenous creamy discharge was most common, observed in 139 patients(69.5%).

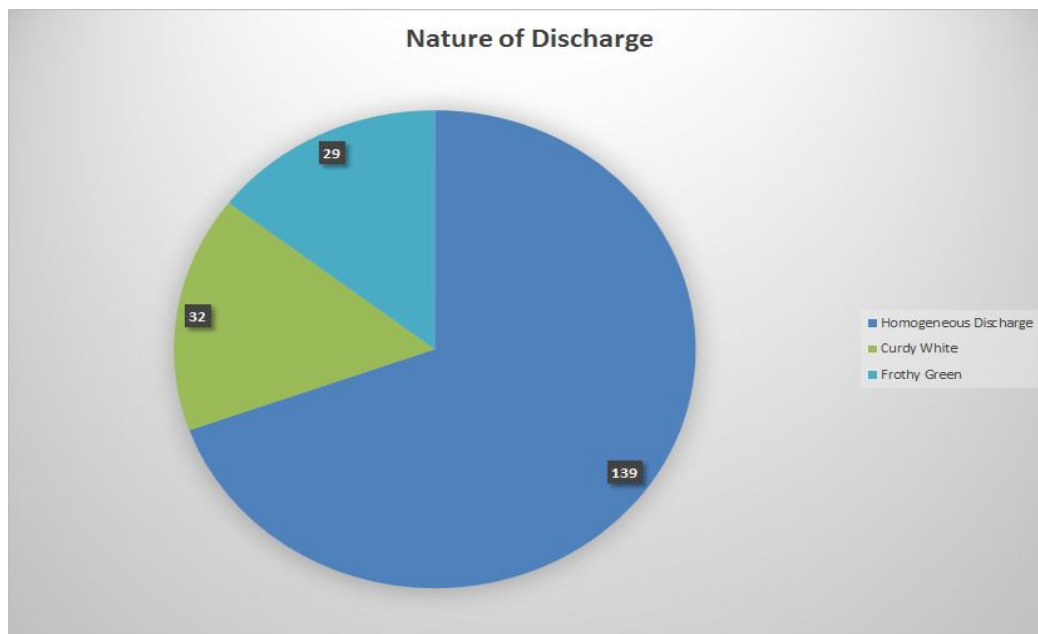


Figure 6

**pH of the vaginal discharge:**

For all patients in our study, pH of the vaginal discharge was tested using narrow range litmus paper held with forceps and dipped into the discharge and comparing with the given colour scale.

pH was  $< 4.5$  in 75 patients (37.5%) and  $\geq 4.5$  in 125 patients (62.5%).

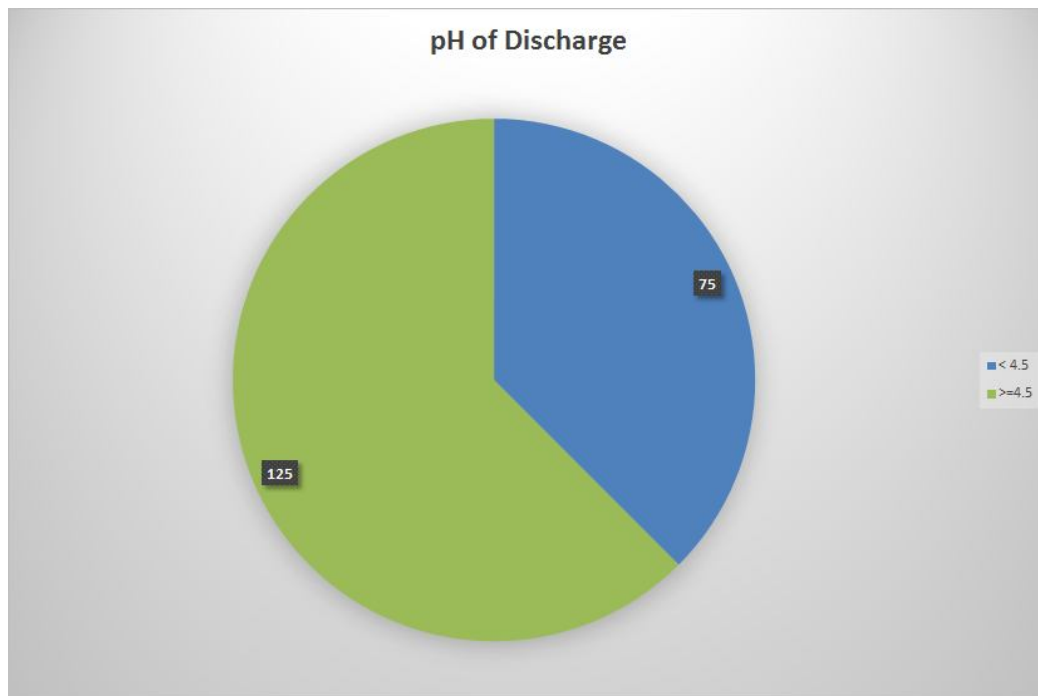


Figure 7

#### **WET MOUNT EXAMINATION FOR TRICHOMONAS VAGINALIS:**

Two high vaginal swabs were taken from all 200 patients in our study. One was used to immediately prepare a wet mount using normal saline and observed using light microscopy for *Trichomonas vaginalis* organisms. Of the 200 studied, 20 patients (10%) were positive for TV.

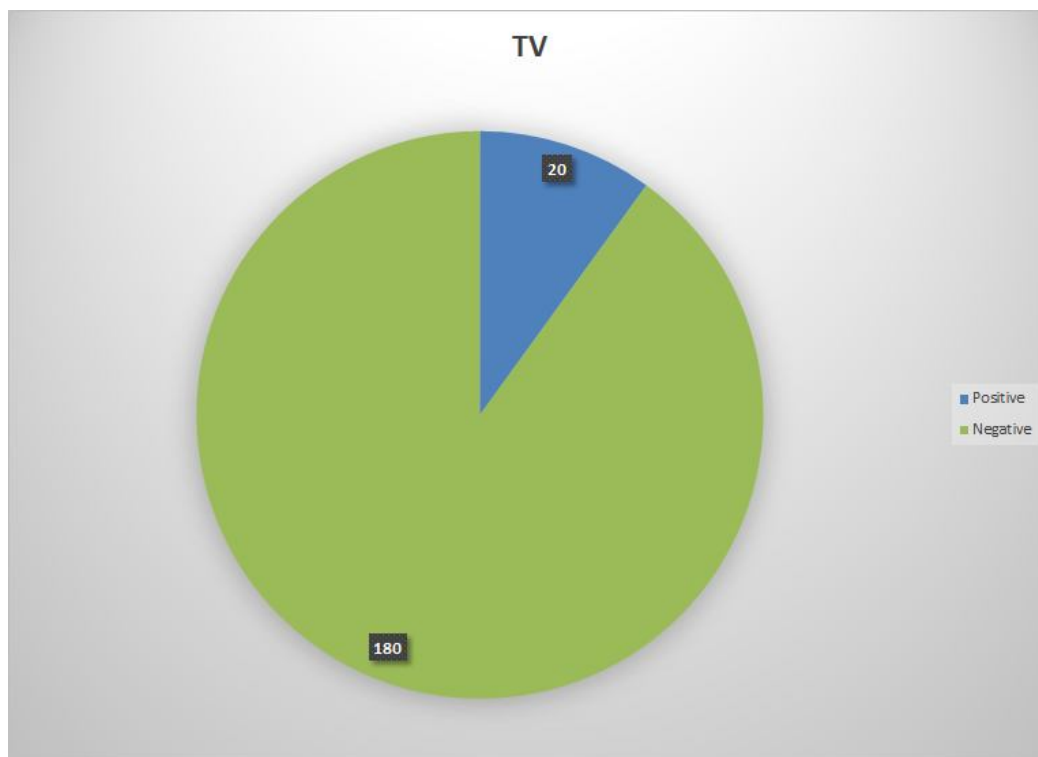


Figure 8

#### **GRAM STAIN FOR BACTERIAL VAGINOSIS:**

Gram staining was done using the second swab in the microbiology laboratory. Bacterial vaginosis was scored using Nugent criteria as described before. Out of the 200 cases, 120 cases were positive for BV (score 7-10), 30 cases were in the intermediate group (score 4-6) and 50 cases were negative for BV (score 0-3).

Nugent score	No. of cases	percentage	Interpretation
7-10	120	60%	Positive
4-6	30	15%	Negative (intermediate)
0-3	50	25%	Negative

Table 6

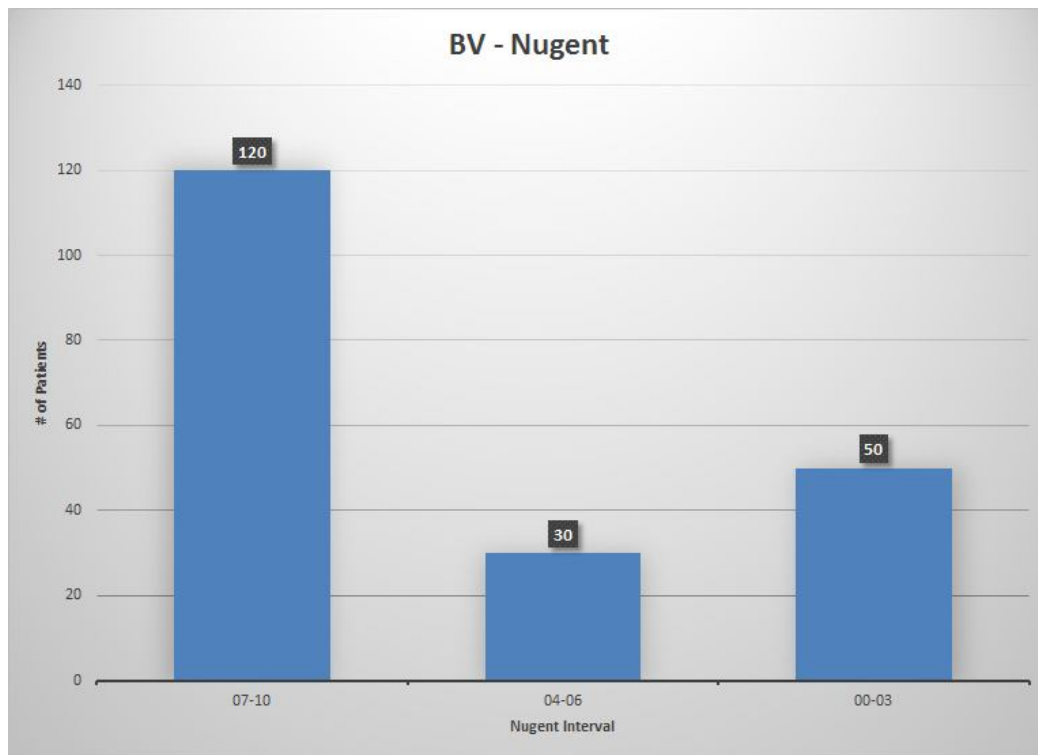


Table 9

### GRAM STAIN FOR CANDIDA:

In the same gram stain the presence of candida was also studied. Candidiasis was diagnosed when budding yeast cells along with pseudo hyphae were observed. Of the 200 cases, 33(16.5%) were positive for candidiasis based on the above criteria.

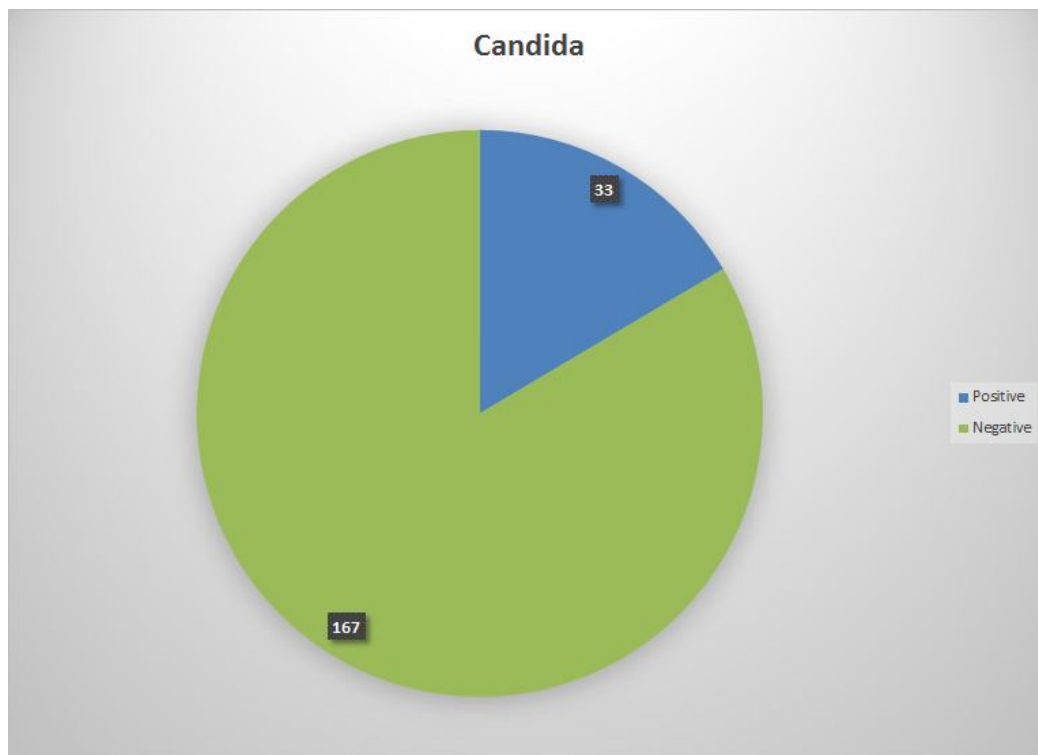


Figure 10

## EVALUATION OF PATIENTS WITH TRICHOMONAS VAGINALIS:

### 1. Age distribution :

Of the 20 patients diagnosed to have Trichomoniasis, the most common age group was 35-40years.

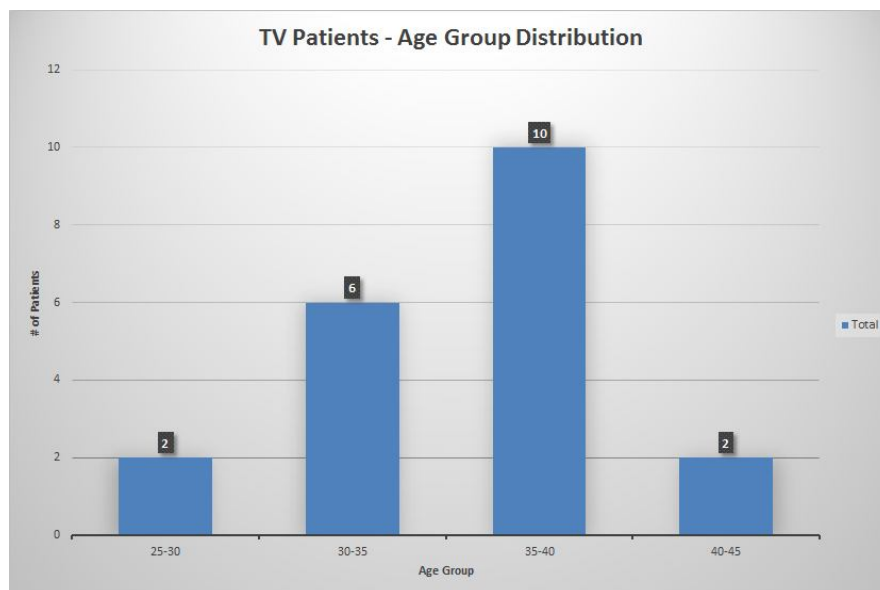
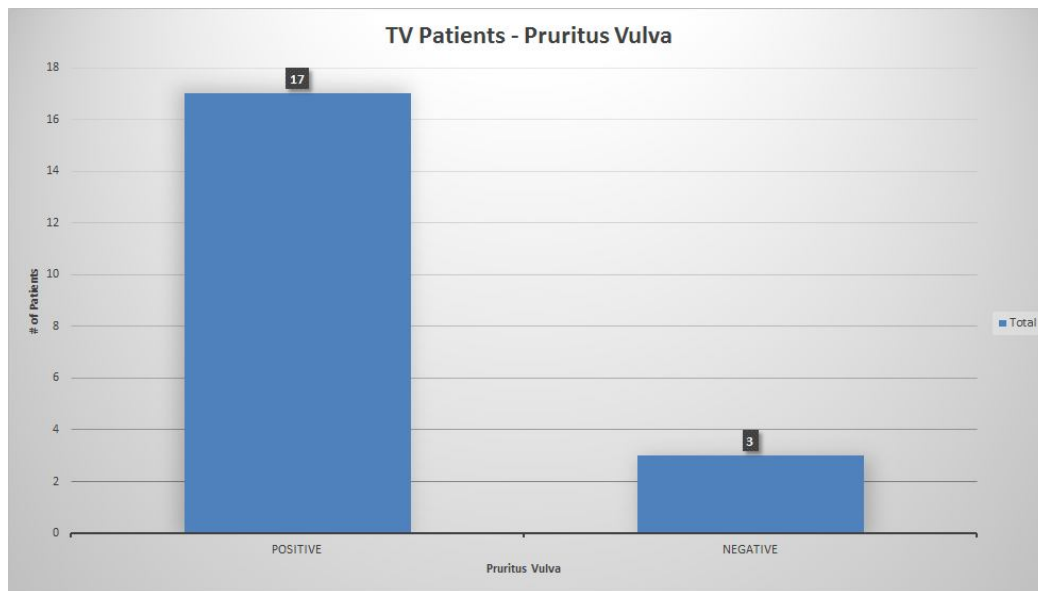


Figure 11

## 2. Association with pruritus:

Among the 20 patients with TV, 17 patients (85%) had pruritus vulva and this association was statistically significant.



**Figure 12**



### Association between Pruritus vulva and TV

Sl.no	Pruritus vulva	Wet Mount for TV		Statistical inference
		Positive (n=20)	Negative (n=180)	
1	Present	17(85%)	44(24.4%)	$X^2=31.138$ Df=1 .000<0.05 Significant
2	Absent	3(15%)	136(75.6%)	

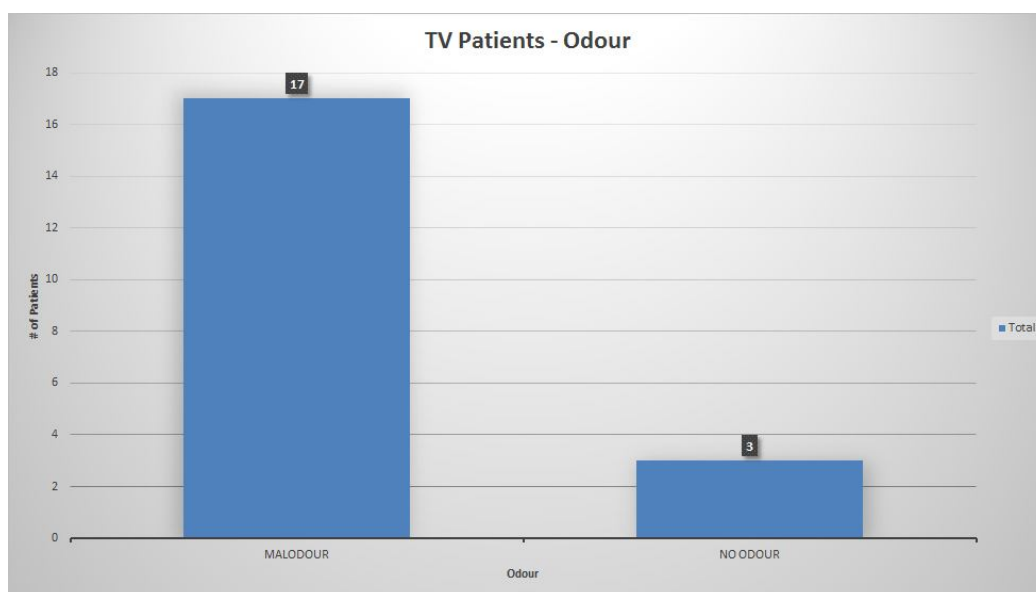
**Table 7**

**Statistical test:** Chi-square test was used in the above table

**Inference:** The above table reveals that there is a significant association between Pruritus vulva of the patients and TV. Hence, the calculated value less than table value (.000<0.05).

### 3. Association with Odour of discharge:

17 (85%) of the 20 patients with TV complained of malodourous discharge and this association was statistically significant.



**Figure 13**

### Association between odour of the discharge and TV

Sl.no	Odour	Wet Mount for TV		Statistical inference
		Positive (n=20)	Negative (n=180)	
1	Malodour	17(85%)	95(52.8%)	$X^2=7.585$ Df=1 .006<0.05 Significant
2	No odour	3(15%)	85(47.2%)	

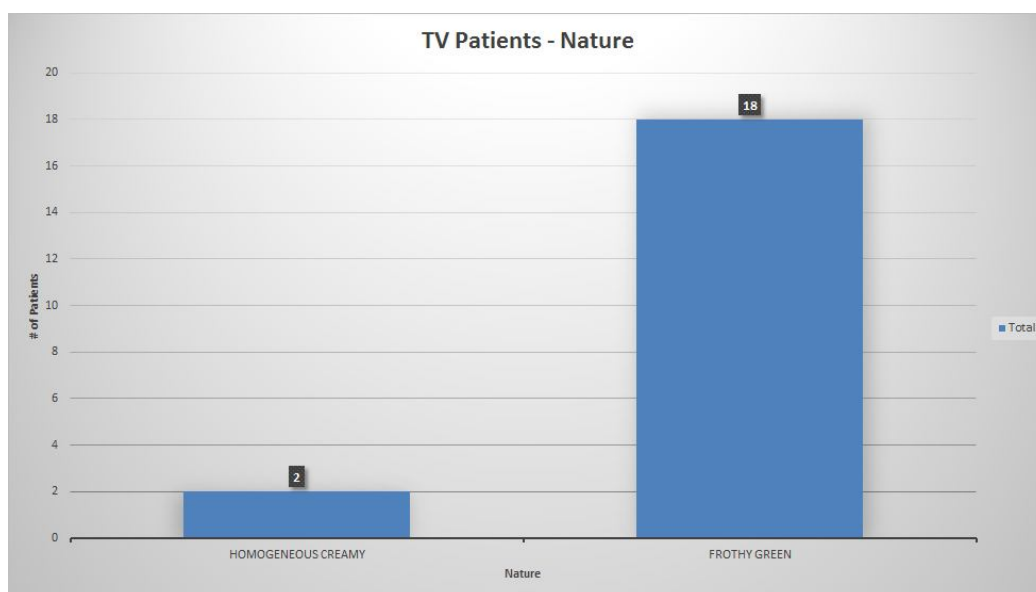
**Table 8**

**Statistical test:** Chi-square test was used in the above table

**Inference:** The above table reveals that there is a significant association between malodourous discharge of the patients and TV. Hence, the calculated value less than table value (.006<0.05).

#### 4. Association with nature of the discharge:

Of the 20 patients with TV, 18(90%) had a frothy green discharge and this association was statistically significant.



**Figure 14**

### Association between nature of the discharge and TV

Sl.no	Nature	Wet Mount for TV		Statistical inference
		Positive (n=20)	Negative (n=180)	
1	Homogenous creamy	2(10%)	137(76.1%)	$X^2=102.235$ Df=2 .000<0.05 Significant
2	Curdy white	0	32(17.8%)	
3	Frothy green	18(90%)	11(6.1%)	

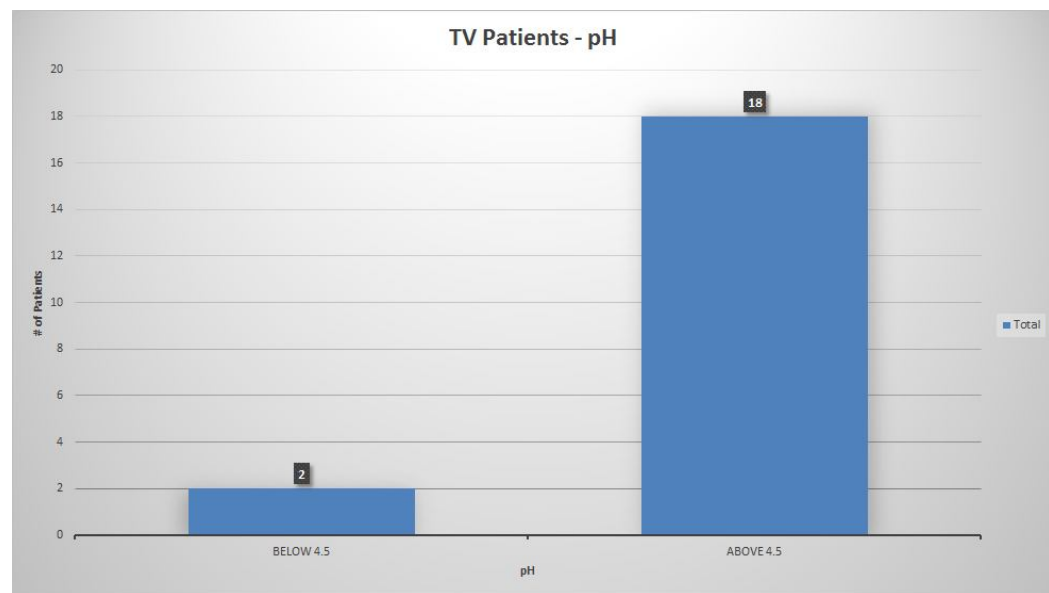
**Table 8**

**Statistical test:** Chi-square test was used in the above table

**Inference** The above table reveals that there is a significant association between frothy green discharge and TV. Hence, the calculated value less than table value (.000<0.05).

### 5. Association with pH of the discharge:

Among the 20 patients with TV, 18(90%) patients had vaginal discharge with  $\text{pH} \geq 4.5$  and this association was statistically significant.



**Figure 15**

**Association between pH of the vaginal discharge and TV**

Sl.no	PH	Wet Mount for TV		Statistical inference
		Positive (n=20)	Negative (n=180)	
1	Below 4.5	2(10%)	73(406.6%)	$X^2=7.170$ Df=1 .007<0.05 Significant
2	Above 4.5	18(90%)	107(59.4%)	

**Table 9**

**Statistical test:** Chi-square test was used in the abovetable

**Inference:** The above table reveals that there is a significant association between the pH of vaginal discharge being  $\geq 4.5$  and TV. Hence, the calculated value less than table value (.007<0.05).

## EVALUATION OF PATIENTS WITH BACTERIAL VAGINOSIS:

### 1. Age distribution :

Of the 120 patients diagnosed to have Bacterial vaginosis, the most common age group was 35-40years.

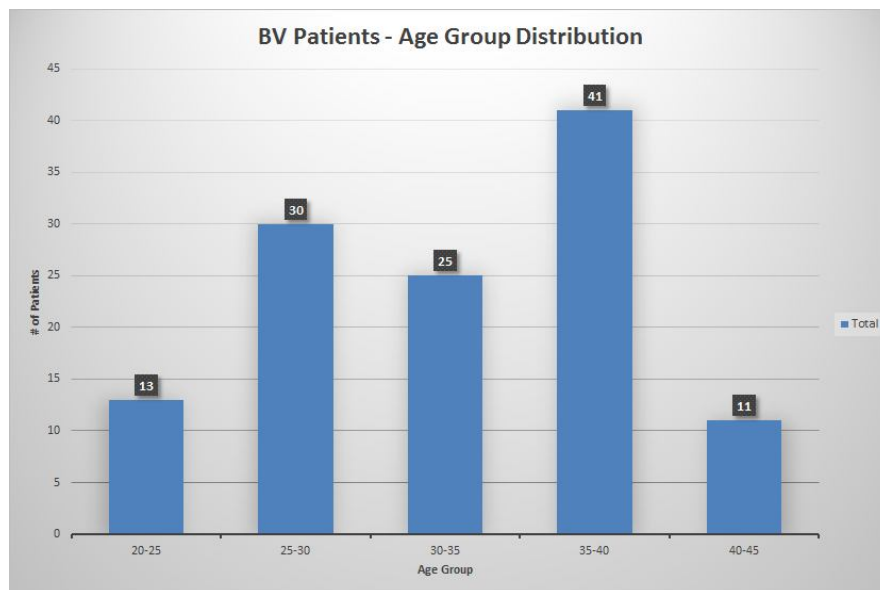


Figure 16



## 2. Association with pruritus:

Among the 120 patients with BV, only 34 patients (28.33%) had pruritus vulva while the remaining 86(71.67%) had no pruritus. Hence the association of pruritus vulva with BV is not statistically significant.

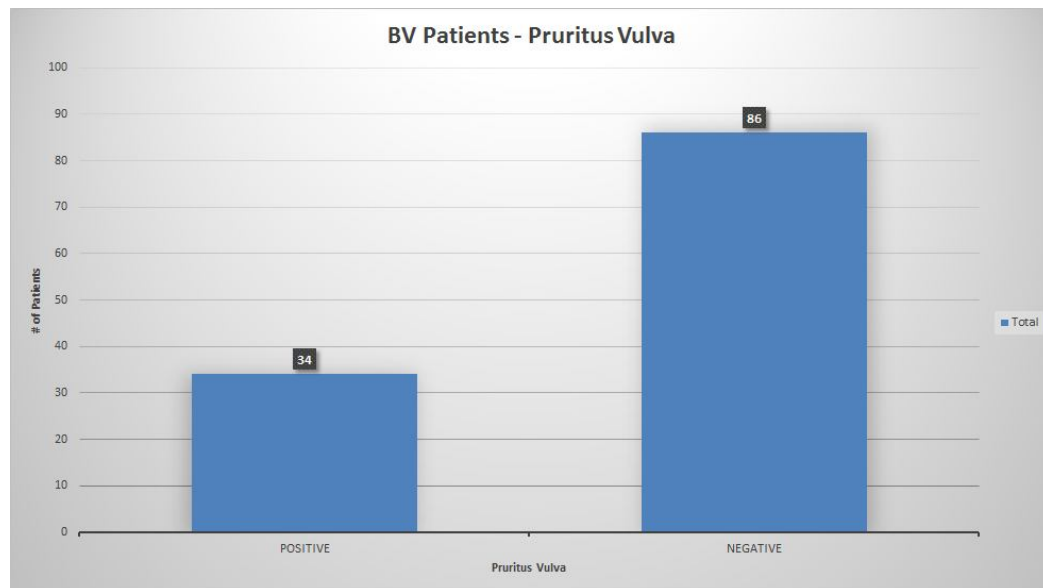
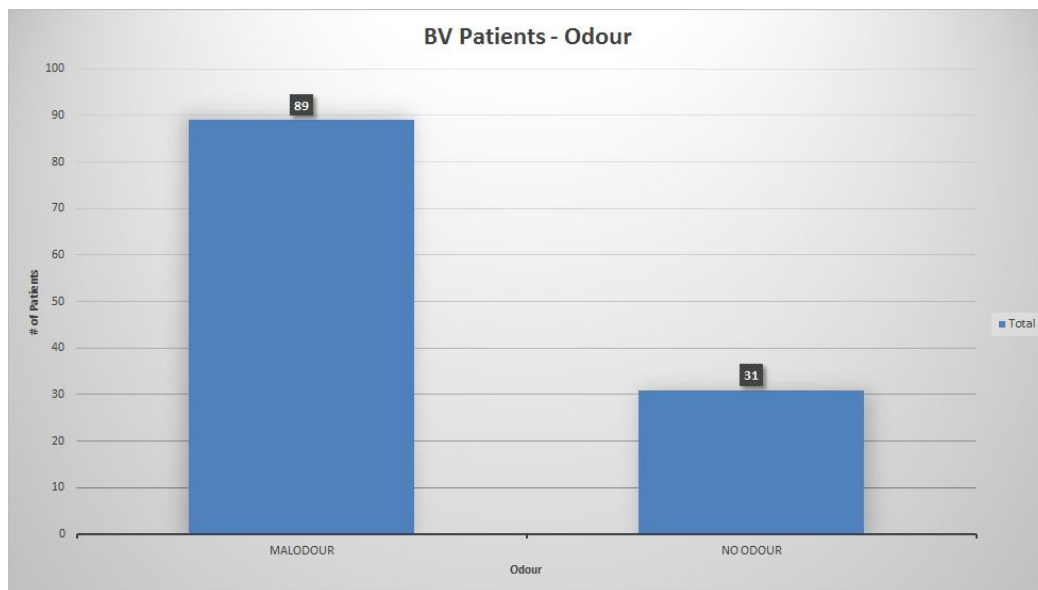


Figure 17

### 3. Association with Odour of discharge:

89 (74.17%) of the 120 patients with BV complained of malodourous discharge and this association was statistically significant.



**Figure 18**

### Association between Odour of the discharge and BV

Sl.no	Odour	Gram stain - BV(Nugent score)			Statistical inference
		7to10 (n=120)	4to6 (n=30)	0to3 (n=50)	
1	Malodour	89(74.2%)	10(33.3%)	13(26%)	$\chi^2=40.591$ $Do=2$ $.000<0.05$ Significant
2	No odour	31(25.8%)	20(66.7%)	37(74%)	

**Table 10**

**Statistical test:** Chi-square test was used in the above table

**Inference:** The above table reveals that there is a significant association between malodour of the discharge and BV. Hence, the calculated value less than table value ( $.000<0.05$ ).

#### 4. Association with nature of the discharge:

Of the 120 patients with BV, 99(82.5%) had a homogenous creamy discharge and this association was statistically significant.

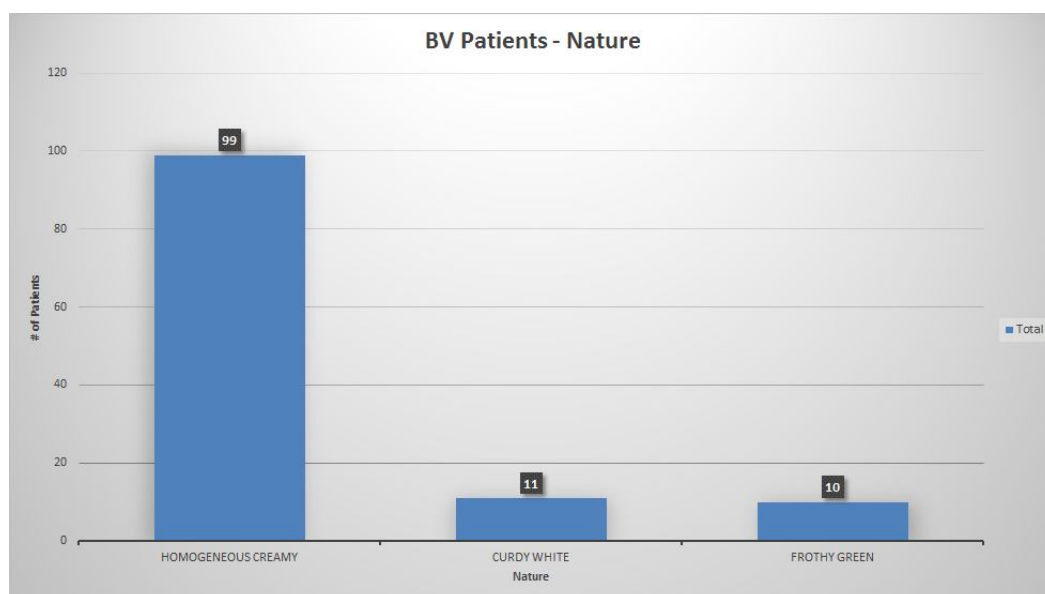


Figure 19

### Association between nature of the discharge and BV

Sl.no	Nature	Gram stain – BV(Nugent score)			Statistical inference
		7to10 (n=120)	4to6 (n=30)	0to3 (n=50)	
1	Homogenous creamy	99(82.5%)	15(50%)	25(50%)	$X^2=24.455$ $Do=4$ $.000<0.05$ Significant
2	Curdy white	11 (9.2%)	7 (23.3%)	14 (28%)	
3	Frothy green	10(8.3%)	8(26.7%)	11(22%)	

**Table 11**

**Statistical test:** Chi-square test was used in the above table

**Inference:** The above table reveals that there is a significant association between homogenous creamy nature of the discharge and BV. Hence, the calculated value less than table value ( $.000<0.05$ ).

### 5. Association with pH of the discharge:

Among the 120 patients with BV, 101(84.17%) patients had vaginal discharge with pH  $\geq 4.5$  and this association was statistically significant.

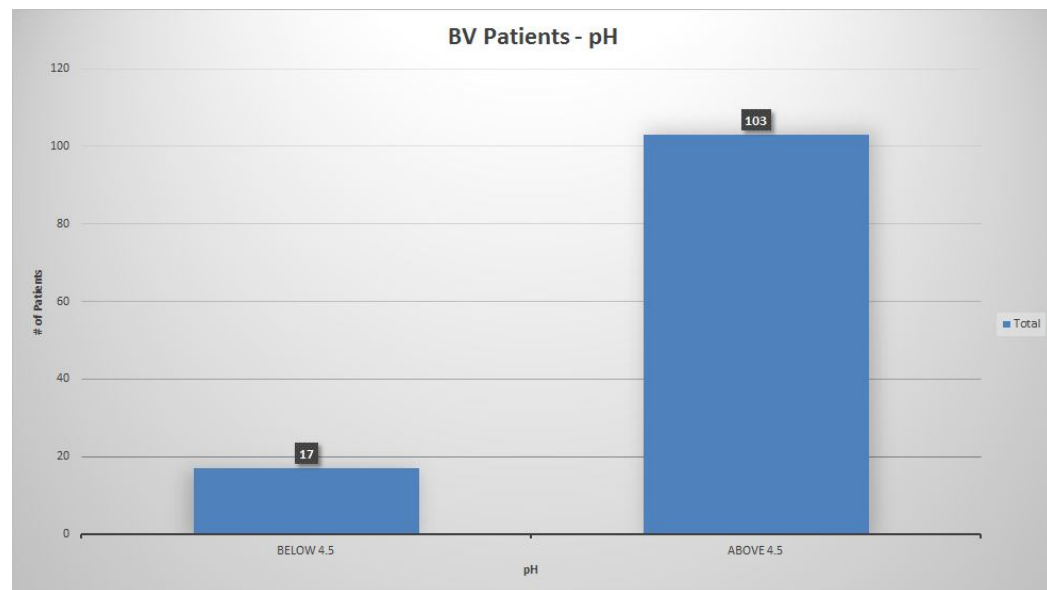


Figure 20

### Association between pH of the discharge and BV

Sl.no	PH	Gram stain – BV(Nugent score)			Statistical inference
		7to10 (n=120)	4to6 (n=30)	0to3 (n=50)	
1	Below 4.5	17(14.2%)	19(63.3%)	39(78%)	$X^2=71.410$ $Do=2$ $.000<0.05$ Significant
2	Above 4.5	103(85.8%)	11(36.7%)	11(22%)	

**Table 12**

**Statistical test:** Chi-square test was used in the above table

**Inference:** The above table reveals that there is a significant association between the pH of vaginal discharge being  $\geq 4.5$  and BV. Hence, the calculated value less than table value ( $.000<0.05$ ).

## EVALUATION OF PATIENTS WITH CANDIDIASIS:

### 1. Age distribution :

Of the 33 patients diagnosed to have candidiasis, the most common age group was 35-40years (10 patients) and an almost equal number (9 patients) were in the 25-30years age group and 8 patients in the 30-35years age group.

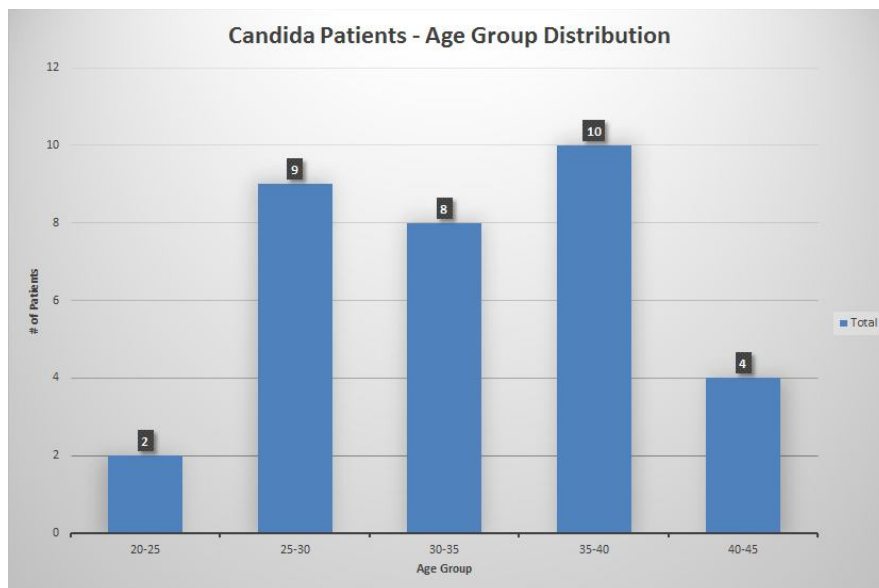
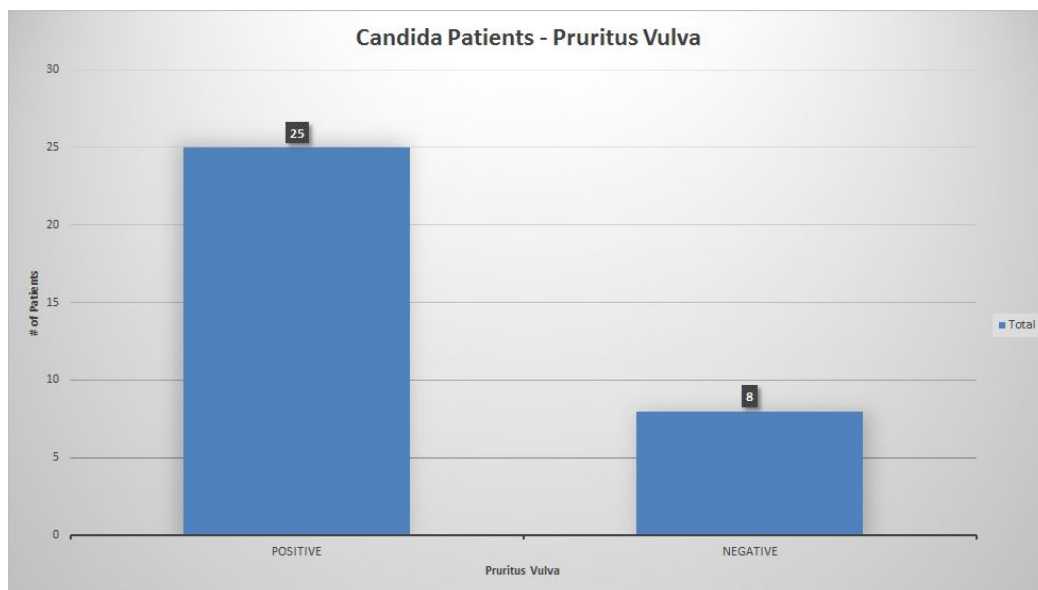


Figure 21



## 2. Association with pruritus:

Among the 33 patients with candidiasis, 25 patients (75.76%) had pruritus vulva and this association was statistically significant.



**Figure 22**

### Association between Pruritus vulva and Candidiasis

Sl.no	Pruritus vulva	Gram stain - Candida		Statistical inference
		Positive (n=33)	Negative (n=167)	
1	Present	25(75.8%)	36(21.6%)	$X^2=38.188$ $Do=1$ $.000<0.05$ Significant
2	Absent	8(24.2%)	131(78.4%)	

**Table 13**

**Statistical test:** Chi-square test was used in the above table

**Inference:** The above table reveals that there is a significant association between Pruritus vulva and Candidiasis. Hence, the calculated value less than table value ( $.000<0.05$ ).

### 3. Association with Odour of discharge:

20 (60.6%) of the 33 patients with candidiasis complained of malodorous discharge and this association was not statistically significant.

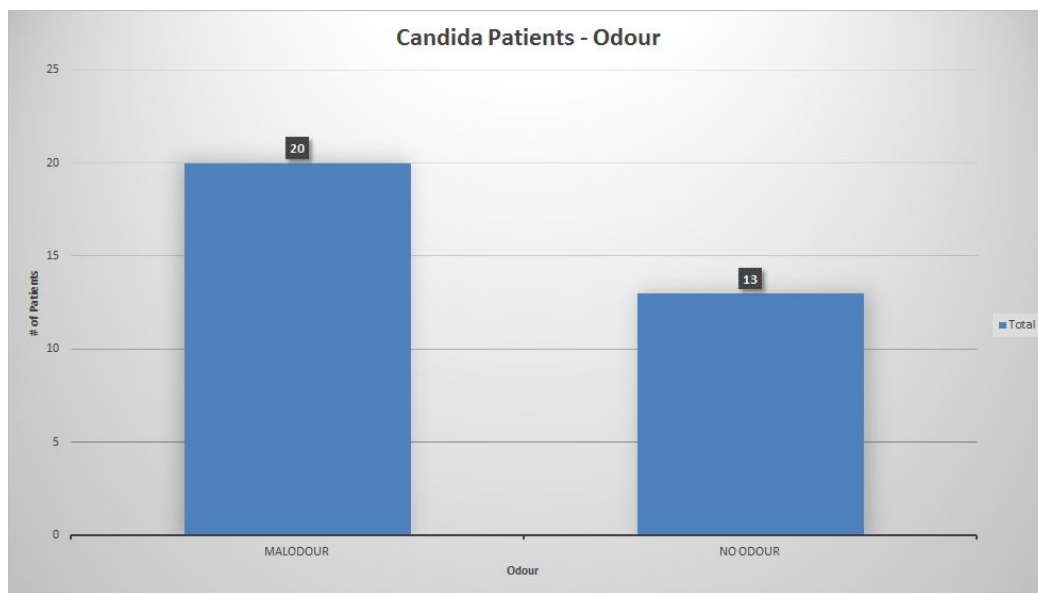
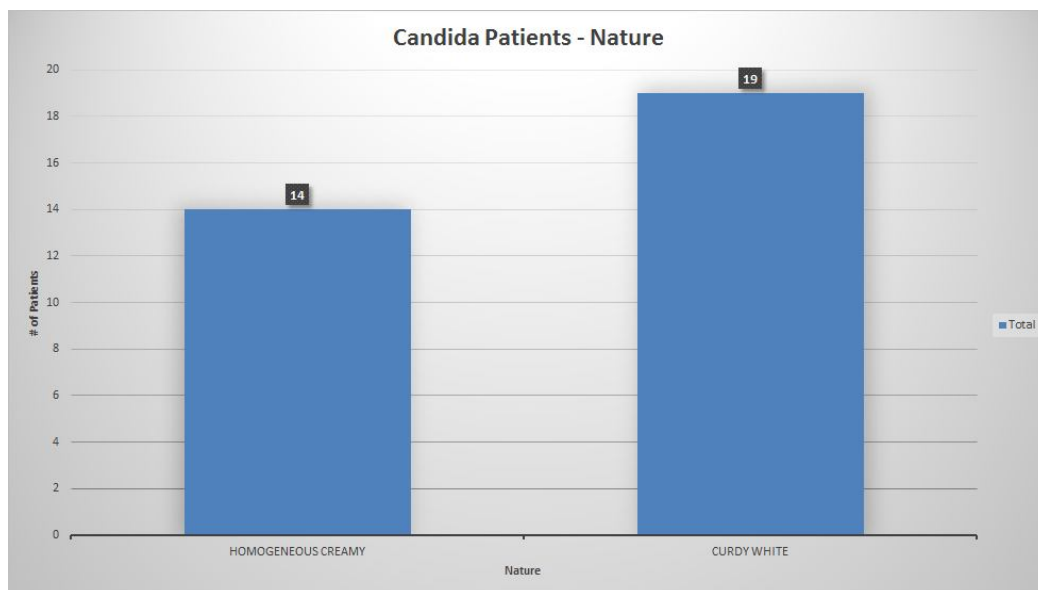


Figure 23

#### 4. Association with nature of the discharge:

Of the 33 patients with candidiasis, 19(82.5%) had a curdy white discharge and this association was statistically significant.



**Figure 24**

### Association between nature of the discharge and Candidiasis

Sl.no	Nature	Gram stain- Candida		Statistical inference
		Positive (n=33)	Negative (n=167)	
1	Homogenous creamy	14(42.4%)	125(74.9%)	$\chi^2=52.595$ $Do=2$ $.000<0.05$ Significant
2	Curdy white	19(57.6%)	13(7.8%)	
3	Frothy green	0	29(17.4%)	

**Table 14**

**Statistical test:** Chi-square test was used in the above table

**Inference:** The above table reveals that there is a significant association between curdy white nature of the vaginal discharge and Candidiasis. Hence, the calculated value less than table value ( $.000<0.05$ ).

### 5. Association with pH of the discharge:

Among the 33 patients with candidiasis, all (100%) patients had vaginal discharge with pH <4.5 and this association was statistically significant.

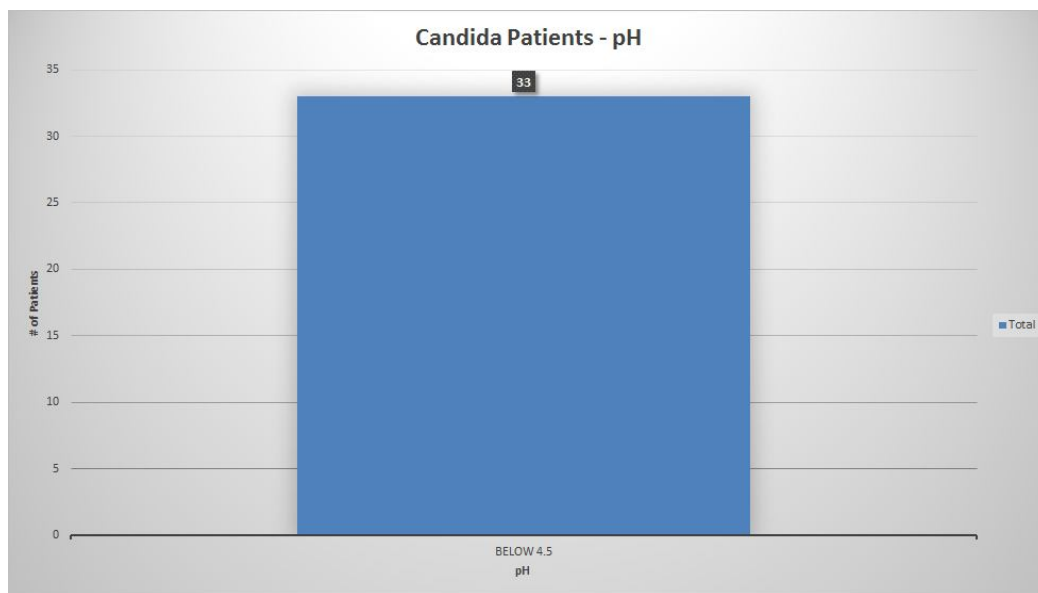


Figure 25

### Association between pH of the discharge and Candidiasis

Sl.no	PH	Gram stain - Candida		Statistical inference
		Positive (n=33)	Negative (n=167)	
1	Below 4.5	33(100%)	42(25.1%)	$X^2=65.868$ $Do=1$ $.000<0.05$ Significant
2	Above 4.5	0	125(74.9%)	

**Table 15**

**Statistical test:** Chi-square test was used in the above table

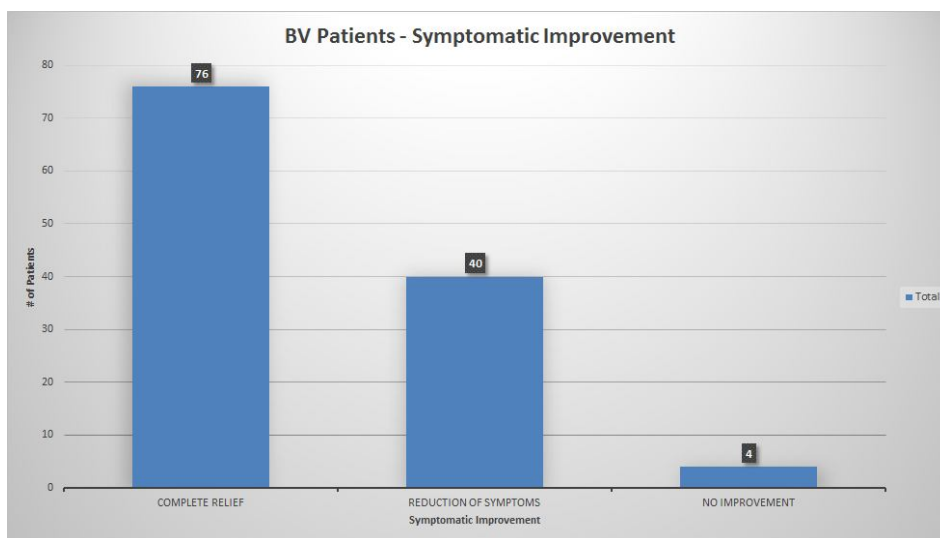
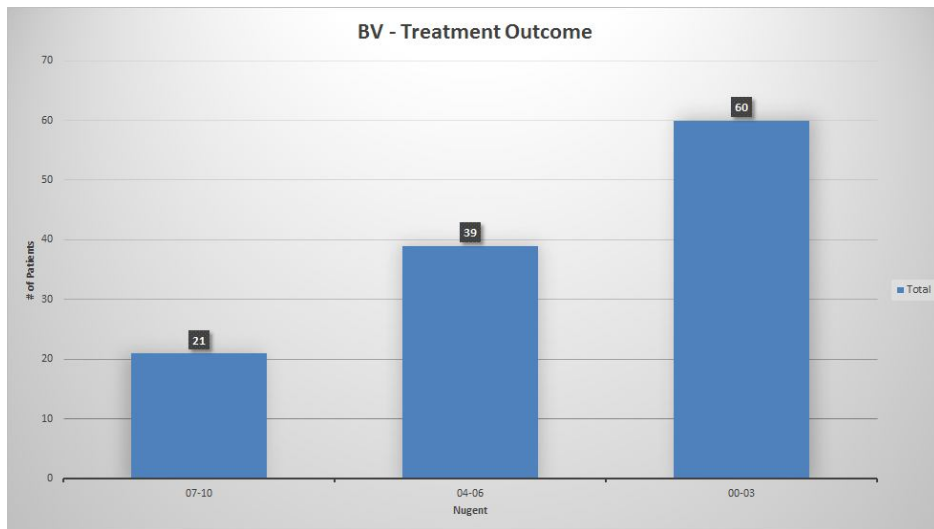
**Inference:** The above table reveals that there is a significant association between pH of the vaginal discharge being  $< 4.5$  and Candidiasis. Hence, the calculated value less than table value ( $.000<0.05$ ).

## EVALUATION OF TREATMENT EFFICACY:

- Efficacy of treatment in BV :

Out of the 120 patients diagnosed with BV, 99 patients(82.5%) were cured bacteriologically after treatment.

Symptomatic improvement in the form of complete relief or reduction of symptoms was seen in 116 patients.



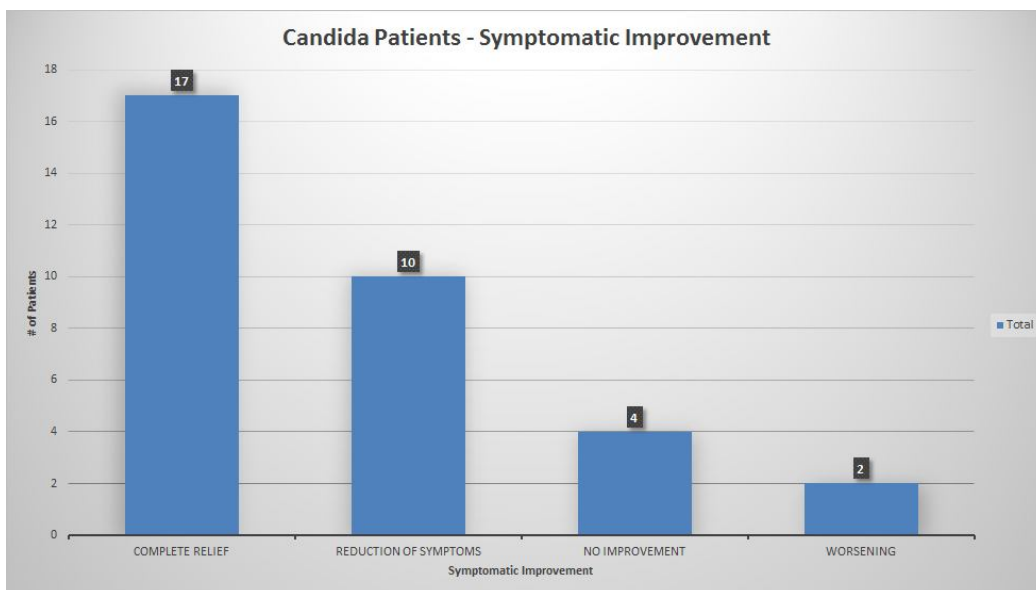
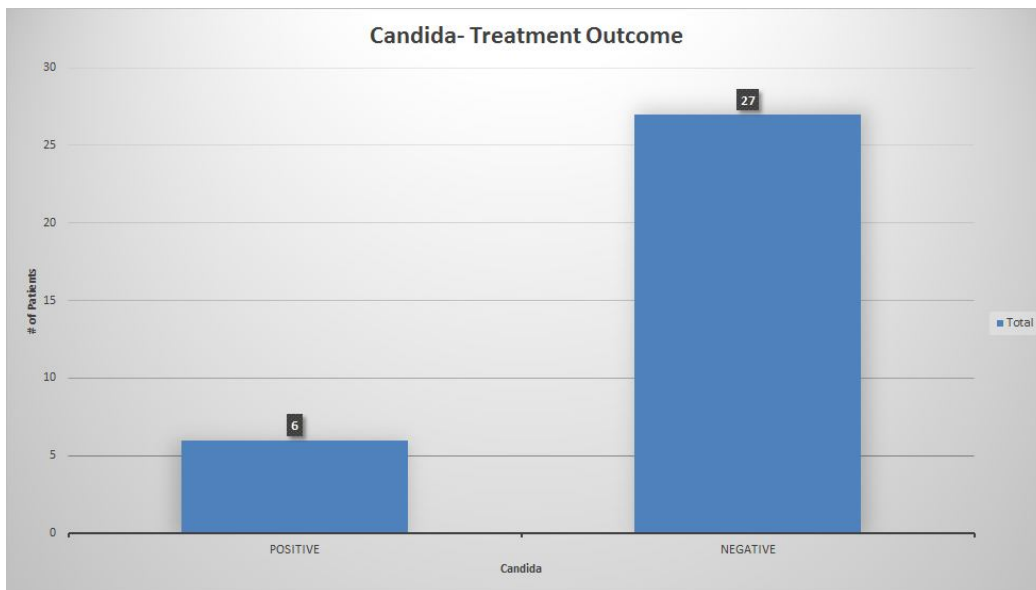
Tables 16 & 17



- **Efficacy of treatment in candidiasis :**

Out of the 33 patients diagnosed with candidiasis, 27 patients (81.8%) were cured after treatment.

Symptomatic improvement in the form of complete relief or reduction of symptoms was seen in 27 patients (81.8%).

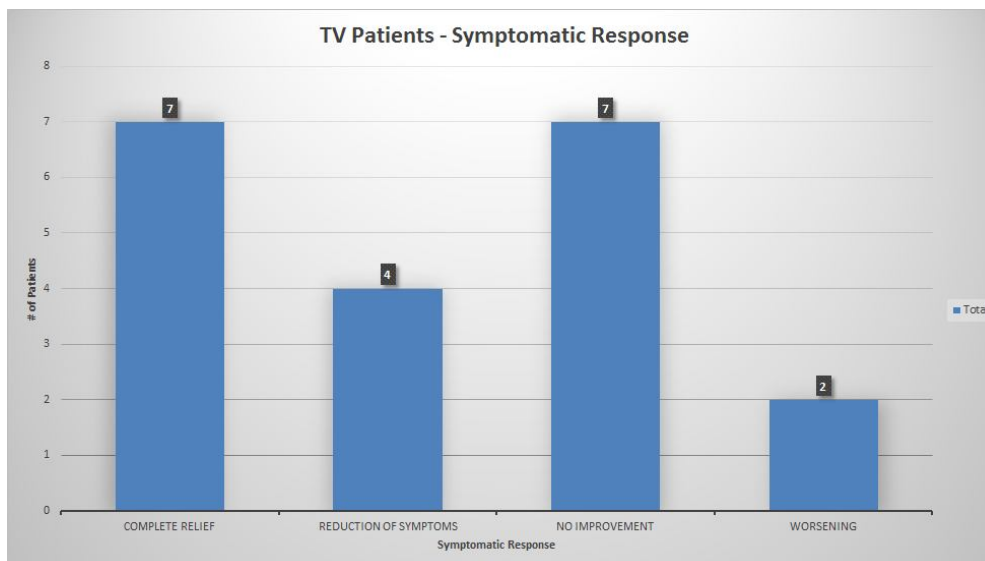
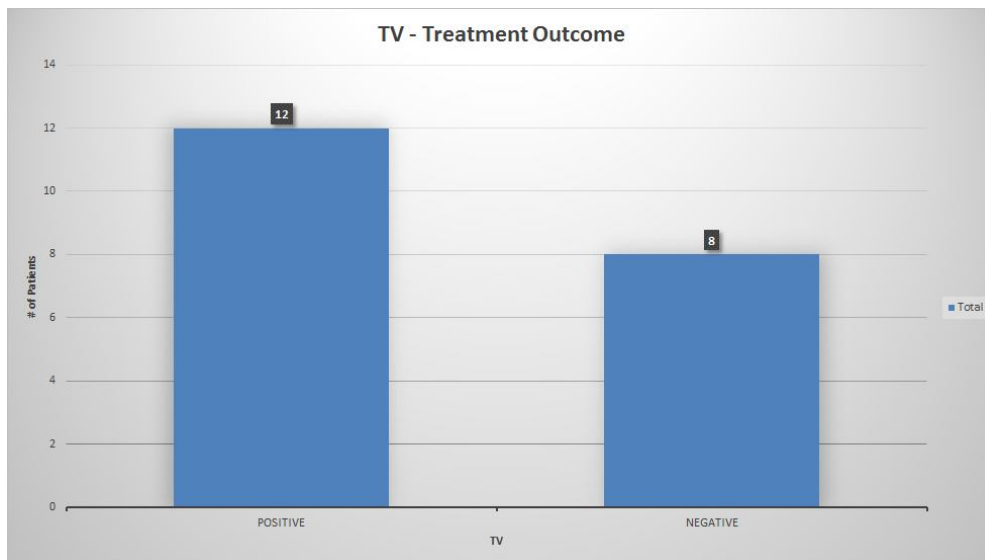


Tables 18 & 19

- **Efficacy of treatment in *Trichomonas vaginitis*:**

Out of the 20 patients diagnosed with trichomoniasis, 8 patients (40%) were cured after treatment.

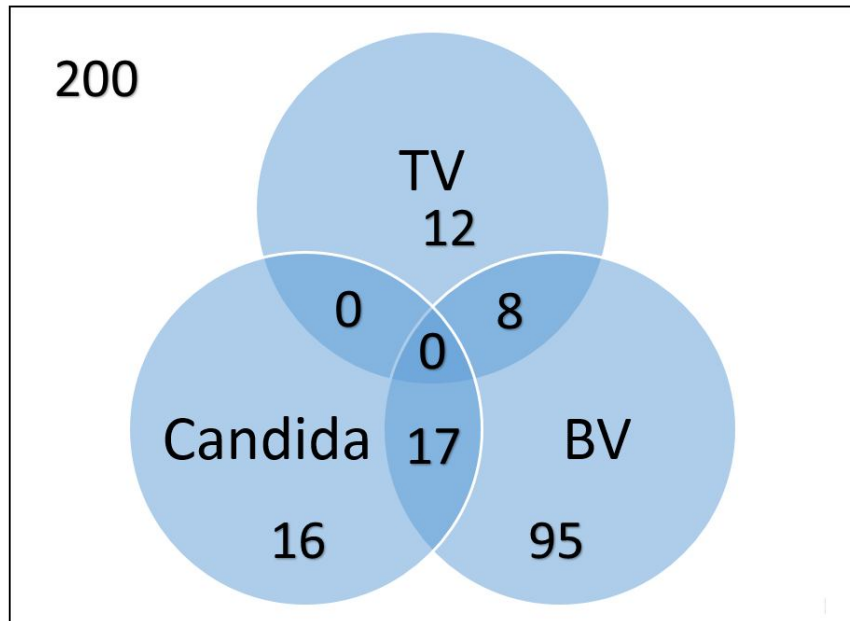
Symptomatic improvement in the form of complete relief or reduction of symptoms was seen in 11 patients (55%).



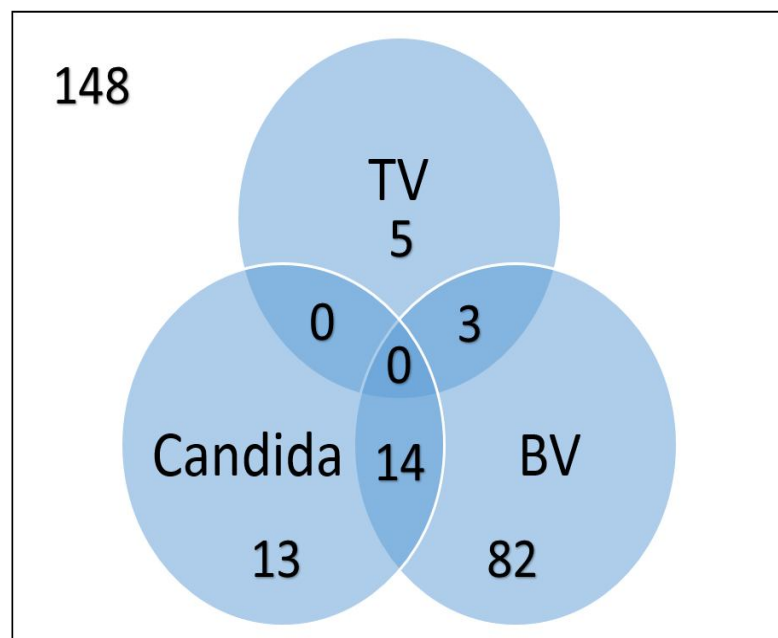
Tables 20 & 21

**Post treatment status of the 148 patients who were positive for one or two of the diseases at the first visit**

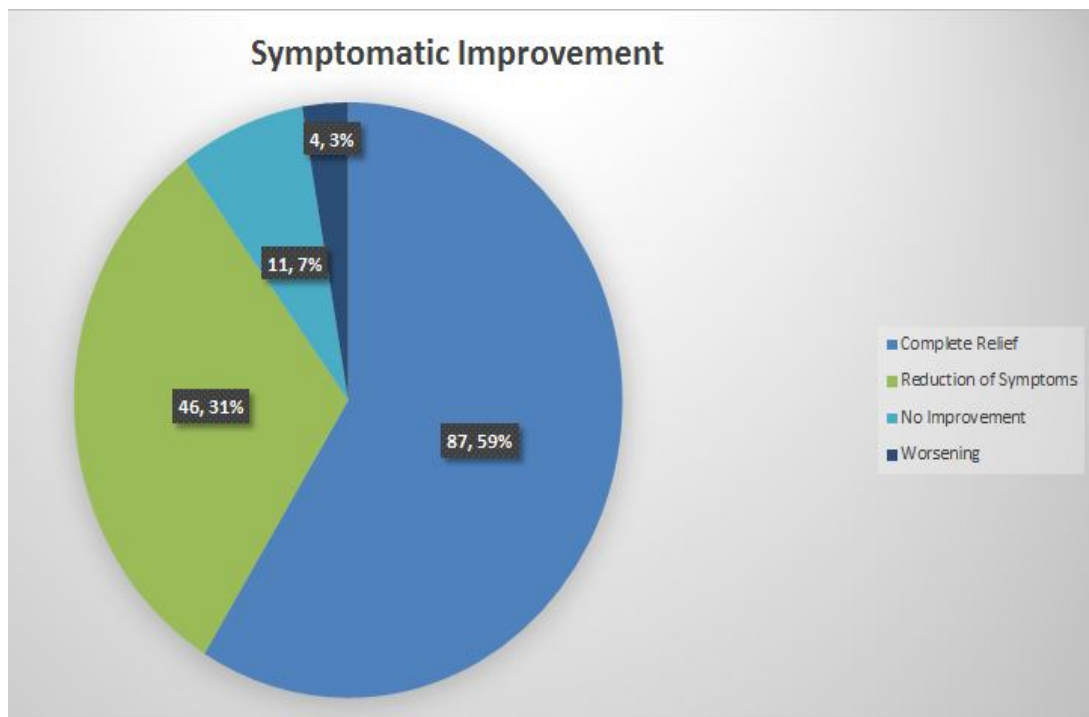
### Distribution of Diseases



### Distribution of Cured Patients



Of the 148 patients who received treatment, 90% of patients had symptomatic relief in the form of complete relief or reduction of symptoms.



## **DISCUSSION**

In our study, 200 women of the reproductive age group presenting with abnormal vaginal discharge to the gynaecology OPD were studied and etiological diagnosis was arrived at in 148 patients. Rekha et al<sup>50</sup> in their study involving similar diagnostic criteria, included 203 patients & established the diagnosis in 146 patients. Other studies by French et al<sup>51</sup>, Ryan et al<sup>52</sup>, Moherdal et al<sup>53</sup> were concurrent with our study, showing that in 10-58% of women presenting with vaginal discharge, no diagnosis could be reached using the diagnostic methods under consideration.

The common age group of patients in our study was 35-40 years. In other studies by Rekha et al<sup>50</sup>, Ryan et al<sup>52</sup>, Thulkar et al<sup>5</sup>, Sharma et al<sup>54</sup>, the most common age group was 25-30 years. This observation may be a reflection of the later age at marriage and sexual intercourse in the community or due to hesitation of the younger age group in our community to come out with these problems.

In our study, the most common cause of abnormal vaginal discharge in the reproductive age group was Bacterial vaginosis (60%). This is in accordance to various studies: Thulkar et al – 37.5%., Renu et al<sup>55</sup> – 36.4%, Bhalla. P et al<sup>56</sup> – 32.8%, Sumati AH et al<sup>57</sup> – 58.4%. The differences in incidence of bacterial vaginosis may be due to the type of population under study and the prevalence in the population studied.

Next to the abnormal vaginal discharge, pruritus vulva was the most common presenting complaint in patients (30.5%) in our study. Similar finding was also noted in the study by Rekha et al<sup>50</sup>.

Bacterial vaginosis was associated with malodourous vaginal discharge in 74.2% of cases, a homogenous creamy discharge in 82.5% of cases and a pH of > 4.5 in 84.5% of cases and all these associations were statistically significant.

Candidiasis was associated with pruritus in 75.8% cases, a curdy white discharge in 82.5% cases and pH < 4.5 in 100% cases and all these associations were statistically significant.

Trichomoniasis was associated with malodorous vaginal discharge in 85% of cases, pruritus in 85% cases, a frothy green discharge in 90% of cases and  $\text{pH} \geq 4.5$  in 90% of cases and all these associations were statistically significant.

Studies by Rekha et al<sup>50</sup>, French et al<sup>51</sup>, Sanchez et al<sup>58</sup>, Rao et al<sup>5</sup> in accordance to our study showed that nature of the vaginal discharge may be a useful criterion in differentiating the common causes of vaginal discharge.

From our study we can infer the most probable cause of the vaginal discharge by correlating the nature, odour, pH of the discharge and association with pruritus. For example, a malodorous homogenous creamy discharge with  $\text{pH} > 4.5$ , is most probably due to bacterial vaginosis. A malodorous, frothy green discharge associated with pruritus and a  $\text{pH} > 4.5$  is most probably due to Trichomoniasis. A curdy white discharge of  $\text{pH} < 4.5$  associated with pruritus but without any odour, is most probably due to Candidiasis. In concurrence to studies by Rao et al<sup>5</sup>, French et al<sup>51</sup>, Moherdaul et al<sup>53</sup> and Vishwanath et al<sup>2</sup>, these findings help in the syndromic management of abnormal vaginal discharge, especially in developing countries where appropriate facilities for diagnosing the exact cause are not available.

In our study, the efficacy of clotrimazole (200mg) and clindamycin (100mg) short course (3 days) intra-vaginal therapy in achieving microbiological cure was 79% (117 of the 148 treated patients) and symptomatic cure was 90% (133 of the 148 patients who were treated).

The difference in the microbiological cure and symptomatic improvement may be due to the belief of the patients that the treatment given to them will surely cure their condition and hence their perceived improvement of symptoms even when actual cure is not established.

The cure rate for Bacterial vaginosis in our study is 82.5% (99 of the 120 treated patients). Faro S et al<sup>59</sup> observed cure rates of 73.7% in their study on effectiveness of clindamycin vaginal preparations in BV. Studies by Mikamo et al<sup>14</sup> showed similar cure rates for oral & vaginal clindamycin in treatment of BV. According to the recent Cochrane review<sup>16</sup>, cure rates in BV were similar for oral clindamycin, topical clindamycin, oral metronidazole and topical metronidazole. Donders et al<sup>20</sup> reported that antifungal therapy cured simultaneously BV in 70% patients in their study. Sanchez S et al<sup>21</sup> reported that combined antifungal and metronidazole topical therapy achieved better cure rates in BV than metronidazole alone. Taking into consideration all the above data and quoting the cure rates achieved by our treatment we could suggest that intra-vaginal



clindamycin & clotrimazole short course therapy is a safe and effective alternate to the traditional 7-14 day oral metronidazole therapy.

Our treatment acquired 81.8% cure rates in candidiasis. This is in accordance to observations of the Clinical Effectiveness Group<sup>22</sup> that both vaginal & oral azoles have similar cure rates of 80-95% in vulvovaginal candidiasis.

In our study, the cure rate for Trichomoniasis was only 40% (8 out of 20). This is in accordance to the study by duBouchet L et al<sup>49</sup> who observed cure rates of only 12% for vaginal clotrimazole compared to 80% for oral metronidazole. So it can be recommended that though our short course intra-vaginal therapy is effective in the other two conditions, patients in whom trichomoniasis is diagnosed or strongly suspected based on clinical symptoms and observations should preferably be given oral metronidazole.

## **SUMMARY**

Abnormal vaginal discharge is a common complaint of many patients attending the gynaecology outpatient department.

The most common age group of patients in the study was 35-40 years.

Using simple laboratory techniques like wet mount saline microscopy and gram staining identified the cause in 74% patients.

Bacterial vaginosis was the most commonly identified cause in 60% patients, followed by candidiasis in 16.5% and trichomoniasis in 10%.

Pruritus vulva was the next common complaint to vaginal discharge seen in 30.5% patients.

The association of Bacterial vaginosis with a malodourous, homogenous creamy discharge with a  $\text{pH} \geq 4.5$  was statistically significant.

The association of candidiasis with pruritus and a curdy white vaginal discharge of  $\text{pH} < 4.5$  was statistically significant.

The association of trichomoniasis with pruritus, a malodourous frothy green vaginal discharge and a  $\text{pH} \geq 4.5$  was statistically significant.

Short course (3 days) intra-vaginal clotrimazole (200mg) and clindamycin (100mg) was effective in curing bacterial vaginosis and candidiasis in more than 80% of patients. But the cure rate for trichomoniasis was only 40%.

Symptomatic improvement was seen in a higher proportion of patients (90%) than actual microbiological cure.

## **CONCLUSION**

Abnormal vaginal discharge is a common complaint in women of the reproductive age group. It is the role of the clinician to conclude if the discharge is physiological or pathological and arrive at a proper diagnosis before institution of treatment.

In a resource constrained setting, the addition of simple office diagnostic tests like wet mount saline microscopy and gram staining can aid in arriving at a more accurate diagnosis than what is reached by symptomatology and clinical examination alone.

Short course intra-vaginal therapy for three days employing 200mg clotrimazole and 100mg clindamycin is a safe and effective alternative to oral antimicrobial therapy for treatment of abnormal vaginal discharge especially in patients with side effects or intolerance to oral preparations and in those with poor compliance to longer duration of therapy as there is always the problem of drug resistance developing in the community due to inadequate treatment.

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## PROFORMA

NAME :

AGE :

OP NO :

SOCIOECONOMIC STATUS :

PRESENTING COMPLAINTS:

VAGINAL DISCHARGE :

DURATION :

NATURE :

HOMOGENOUS CREAMY ☐

CURDY WHITE ☐

FROTHY GREEN ☐

PRURITUS VULVA : ☐ Yes

☐ No

DYSURIA : ☐ Yes

☐ No

DYSPAREUNIA : ☐ Yes

☐ No

MENSURUAL HISTORY :

CYCLES

L.M.P:

**MARITAL HISTORY :**

MARRIED SINCE

ANY SYMPTOMS IN HUSBAND

**OBSTETRIC HISTORY :**

NO. OF CHILDREN

MODE OF DELIVERY

LAST CHILD BIRTH

**PAST HISTORY:**

DIABETES

HISTORY S/O STD

PROLONGED ANTIBIOTIC THERAPY

OCP USE

**CLINICAL EXAMINATION :**

GENERAL CONDITION

PER ABDOMEN

PER SPECULUM

CERVIX & VAGINA - ☐ HEALTHY

- ☐ CONGESTED

- ☐ EROSION

**NATURE OF VAGINAL DISCHARGE**

HOMOGENOUS CREAMY : ☐

CURDY WHITE : ☐

FROTHY GREEN : ☐

PH: ☐ < 4.5 ☐ ≥ 4.5

**PER VAGINAL EXAMINATION:**

WET MOUNT FOR TRICHOMONAS VAGINALIS : ☐ positive ☐ negative

**GRAM STAIN FOR BACTERIAL VAGINOSIS:**

Nugent score : ☐ 0-3

☐ 4-6

☐ 7-10

GRAM STAIN FOR CANDIDA: ☐ positive ☐ negative

TREATMENT GIVEN : ☐ Yes

☐ No

**FOLLOW UP VISIT:**

WET MOUNT FOR TRICHOMONAS VAGINALIS: ☐ positive ☐ negative

**GRAM STAIN FOR BACTERIAL VAGINOSIS:**

Nugent score : ☐ 0-3

☐ 4-6

☐ 7-10

GRAM STAIN FOR CANDIDA: ☐ positive ☐ negative

**SYMPTOMATIC RESPONSE:**

- ☐ COMPLETE RELIEF
- ☐ REDUCTION OF SYMPTOMS
- ☐ NO IMPROVEMENT
- ☐ WORSENING OF SYMPTOMS

S.NO	Name	Age	OP no.	Pruritus vulva	Odour	Nature	pH	I- TV	I - BV	I - Candida	II- TV	II - BV	II - Candida	Symptomatic Improvement
1	Dhanakodi	42	121005	2	1	1	2	2	1	2	0	3	2	1
2	Shanthi	37	113008	1	2	1	1	2	2	2	0	0	0	0
3	Nirmala	35	121685	1	1	1	2	2	1	2	0	3	2	1
4	Parimala	27	121045	2	2	1	2	2	1	2	0	3	2	1
5	Hemalatha	34	121056	2	1	1	2	2	1	2	0	2	2	1
6	Dhanam	25	121055	1	1	1	2	2	1	2	0	3	2	1
7	Durgadevi	27	121076	2	1	1	2	2	1	2	0	3	2	2
8	Revathy	28	121097	2	2	1	2	2	1	2	0	2	2	1
9	Devika	37	121103	2	2	3	2	2	2	2	0	0	0	0
10	Sumathy	35	121089	1	1	3	2	1	3	2	2	0	0	1
11	Ganga	35	121301	1	1	1	2	2	1	2	0	3	2	1
12	Suseela	30	121322	2	1	1	1	2	2	2	0	0	0	0
13	Umapathy	27	121324	1	2	1	2	2	2	2	0	0	0	0
14	Radhiga	29	121318	2	1	1	2	2	1	2	0	3	2	1
15	Pushparani	35	121365	2	2	1	2	2	1	2	0	2	2	2
16	Rajamani	37	121347	2	1	1	2	2	1	2	0	2	2	1

17	Anandhavalli	35	110986	2	1	1	2	2	1	2	0	3	2	1
18	Meenakshi	30	112993	1	1	3	2	1	3	2	1	0	0	4
19	Shanthi	30	111451	1	1	1	1	2	2	2	0	0	0	0
20	Thamaraiselvi	25	112994	2	2	1	1	2	2	2	0	0	0	0
21	Kolanji	35	113111	1	1	2	1	2	1	1	0	3	2	1
22	Sathyaprabha	24	112482	2	1	1	2	2	1	2	0	2	2	2
23	Amudha	40	113000	2	2	3	2	2	2	2	0	0	0	0
24	Prabha	24	112479	2	2	1	2	2	1	2	0	2	2	2
25	Janaki	38	127637	1	2	3	1	2	3	2	0	0	0	0
26	Rajeshwari	38	123667	2	1	1	2	2	1	2	0	2	2	1
27	Faritha	37	110911	1	1	3	2	1	3	2	1	0	0	3
28	Andal	30	110923	2	2	1	2	2	3	2	0	0	0	0
29	Lakshmi	34	110987	1	1	1	2	1	1	2	2	1	1	2
30	Pattu	40	127634	1	1	1	1	2	1	1	0	3	2	1
31	Alamelu	32	127705	2	2	1	1	2	3	2	0	0	0	0
32	Mahendramani	35	127742	2	2	2	1	2	3	2	0	0	0	0
33	Kolanji	28	127746	2	2	2	1	2	2	2	0	0	0	0
34	Chinnapulla	42	127745	2	2	1	2	2	2	2	0	0	0	0
35	Jaicy Rose	37	127001	2	1	1	2	2	1	2	0	3	2	1



36	Samiyammal	38	127018	2	1	3	2	1	2	2	1	0	0	3
37	Karpagavalli	39	127020	2	2	3	1	2	2	2	0	0	0	0
38	Sathyadevi	33	127057	2	1	1	2	2	1	2	0	3	2	1
39	Chinnaponnu	35	127075	2	1	2	1	2	1	1	0	2	2	1
40	Jenita	27	127071	2	2	1	2	2	1	2	0	2	2	2
41	Poongodhai	40	127091	2	1	1	1	2	3	2	0	0	0	0
42	Valli	36	127138	2	2	1	2	2	1	2	0	3	2	2
43	Selvambal	34	127203	2	1	1	2	2	1	2	0	3	2	2
44	Rajeshmary	30	127216	2	1	1	2	2	1	2	0	3	2	2
45	Anuradha	29	127226	2	2	1	2	2	2	2	0	0	0	0
46	Mariyamma	27	127561	1	1	1	1	2	2	1	0	0	1	4
47	Muthurasu	43	127564	2	2	3	1	2	3	2	0	0	0	0
48	Selvi	35	127367	1	1	3	1	1	2	2	2	0	0	1
49	Malliga	40	127353	1	1	1	2	2	1	2	0	3	2	2
50	Chinnamal	44	127374	2	2	1	1	2	2	2	0	0	0	0
51	Mahalakshmi	23	127370	2	1	1	2	2	1	2	0	3	2	2
52	Maheshwari	26	127371	2	1	1	2	2	1	2	0	3	2	2
53	Revathy	35	127373	2	2	1	2	2	1	2	0	2	2	1
54	Vijayakala	31	134579	2	1	1	2	2	1	2	0	3	2	1

55	Sumathy	29	134591	2	2	1	2	2	1	2	0	3	2	1
56	Palaniyayi	25	134580	2	1	1	2	2	1	2	0	3	2	1
57	Amudha	28	134616	2	1	1	2	2	1	2	0	3	2	1
58	Valli	28	134629	1	2	1	1	2	3	1	0	0	1	3
59	Madhiyalagi	35	134658	1	1	3	2	1	1	2	1	1	2	3
60	Thenmozhi	30	134745	2	1	3	2	1	3	2	2	0	0	1
61	Dhanalaksmi	30	134773	2	1	1	2	2	1	2	0	3	2	2
62	Jayalakshmi	39	134791	2	1	1	2	2	1	2	0	3	2	1
63	Rukmani	37	134822	2	2	1	1	2	1	1	0	2	2	2
64	Chitravalli	25	134812	2	2	1	2	2	3	2	0	0	0	0
65	Lusiamary	31	134798	2	1	3	1	2	3	2	0	0	0	0
66	Sandiradevi	32	136194	1	1	2	1	2	1	1	0	3	2	2
67	Jayalakshmi	35	136243	2	1	1	2	2	1	2	0	2	2	1
68	Mary	32	136455	2	2	1	1	2	3	2	0	0	0	0
69	Manjula	32	140018	1	2	2	1	2	1	1	0	1	2	2
70	Chitra	27	140007	2	1	2	1	2	1	1	0	2	2	2
71	Vasuki	35	136500	1	1	1	1	2	1	1	0	3	2	1
72	Sathyarani	27	140024	2	1	1	2	2	3	2	0	0	0	0
73	Hema	33	140262	2	2	3	1	2	3	2	0	0	0	0

74	Malliga	38	140252	1	2	3	2	1	3	2	1	0	0	3
75	Thamaraiselvi	36	140253	2	1	1	2	2	1	2	0	3	2	1
76	Sumathy	37	140266	2	1	1	2	2	1	2	0	2	2	1
77	Thenmozhi	30	140269	2	1	1	2	2	1	2	0	3	2	1
78	Chitra	28	140284	1	1	1	1	2	1	1	0	3	2	1
79	Vijaya	24	140281	2	1	1	2	2	1	2	0	3	2	1
80	Chitradevi	29	140498	2	2	1	1	2	3	2	0	0	0	0
81	Mythili	23	140509	2	2	1	2	2	3	2	0	0	0	0
82	Rani	26	146711	2	1	1	2	2	1	2	0	3	2	1
83	Arayee	34	146776	1	2	1	2	2	1	2	0	1	2	1
84	Poovatha	37	145879	1	1	3	2	1	2	2	1	0	0	2
85	Dhanam	24	146876	2	1	1	2	2	1	2	0	2	2	1
86	Firoz Begam	27	147109	2	1	1	2	2	1	2	0	3	2	1
87	Manjula	34	147137	1	1	2	1	2	3	1	0	0	1	3
88	Deepa	25	147169	2	2	2	1	2	2	2	0	0	0	0
89	Priya	27	147108	2	2	1	2	2	1	2	0	1	2	1
90	Kanagavalli	28	147205	2	1	1	2	2	1	2	0	3	2	2
91	Anbuselvi	37	147356	2	2	2	2	2	2	2	0	0	0	0
92	Barathy	35	147326	1	1	1	2	1	1	2	2	3	2	1

93	Janaki	35	147346	2	1	1	2	2	1	2	0	2	2	2
94	Parvathy	30	147492	1	2	1	1	2	3	1	0	0	2	2
95	Lyla	27	147501	2	1	1	2	2	1	2	0	2	2	2
96	Vanathi	29	147525	2	1	1	2	2	1	2	0	1	2	1
97	Leelavathy	35	147547	1	1	3	1	1	3	2	1	0	0	4
98	anbarasi	37	147552	1	1	1	2	2	1	2	0	3	2	1
99	Kirutniga	35	147587	2	1	2	1	2	1	1	0	3	2	1
100	Mohana	29	147599	2	2	1	1	2	3	2	0	0	0	0
101	Kamala	42	148616	2	2	1	2	2	1	2	0	2	2	1
102	Vaidegi	28	147814	2	1	1	2	2	1	2	0	3	2	1
103	Meenakshi	27	147823	2	2	2	1	2	2	2	0	0	0	0
104	Subha	34	147827	1	1	3	2	1	1	2	2	3	2	1
105	Rajeshwari	42	147831	2	1	1	2	2	1	2	0	2	2	2
106	Prabha	27	147833	2	1	1	2	2	1	2	0	1	2	1
107	gomathy	43	147839	2	2	2	2	2	2	2	0	0	0	0
108	Kala	35	147841	2	2	1	2	2	1	2	0	3	2	1
109	Surya	40	147841	1	1	2	1	2	1	1	0	2	2	1
110	Ramani	44	147856	1	1	3	2	1	1	2	1	2	2	3
111	Saranya	23	147859	2	2	1	2	2	1	2	0	3	2	2

112	Prema	26	147860	2	2	1	1	2	3	2	0	0	0	0
113	Pushpavalli	35	147864	2	1	1	2	2	1	2	0	3	2	2
114	Susaiyammal	31	147872	2	1	1	2	2	1	2	0	2	2	2
115	Patturoja	29	147881	2	2	1	1	2	3	2	0	0	0	0
116	Niroja	25	147895	1	1	1	1	2	3	1	0	0	2	1
117	Karunapathy	28	147900	2	2	1	2	2	1	2	0	1	2	2
118	Tamilpriya	28	147907	1	1	1	2	2	1	2	0	2	2	1
119	Amudha	35	148911	2	2	1	1	2	3	2	0	0	0	0
120	Amsu	30	148916	2	2	3	2	2	1	2	0	1	2	1
121	Parvathy	30	148922	2	1	1	2	2	1	2	0	3	2	2
122	Kokila	39	148928	1	2	3	2	1	2	2	1	0	0	2
123	Mariyam	37	148938	2	2	1	2	2	1	2	0	3	2	1
124	Rajam	25	148946	2	1	1	2	2	3	2	0	0	0	0
125	Kavitha	31	148953	1	2	2	1	2	3	1	0	0	2	2
126	Geetha	23	148961	2	1	1	2	2	1	2	0	1	2	2
127	Lakshmi	35	148968	2	1	1	2	2	1	2	0	2	2	2
128	Dharmambal	35	148972	1	2	1	2	2	1	2	0	3	2	1
129	Dhamayanthi	24	148986	2	1	1	2	2	1	2	0	1	2	2
130	Janani	40	148991	1	2	2	1	2	3	1	0	0	1	3

131	Shobana	24	148999	1	1	1	1	2	1	1	0	3	2	1
132	Rajakumari	38	149007	2	1	1	2	2	1	2	0	2	2	1
133	Gnansundari	38	149015	2	2	1	2	2	1	2	0	3	2	1
134	Parimala	37	149025	2	1	1	2	2	1	2	0	1	2	1
135	Kamatchi	30	149036	1	2	1	1	2	3	1	0	0	2	1
136	Parveen	34	149039	2	1	1	2	2	1	2	0	2	2	2
137	Rekha	40	149047	1	1	3	2	1	1	2	1	3	2	3
138	hemavathy	32	149059	2	2	1	2	2	1	2	0	1	2	1
139	Kannagi	35	149061	2	2	2	1	2	3	2	0	0	0	0
140	Saralmary	28	140069	2	1	2	1	2	3	1	0	0	2	1
141	Tamilselvi	42	149071	1	2	2	1	2	1	1	0	2	2	1
142	Vimala	37	149078	2	1	3	2	2	1	2	0	3	2	1
143	Sivasakthi	38	149083	2	1	1	2	2	1	2	0	2	2	1
144	Solaiammal	39	149087	1	2	1	1	2	2	1	0	0	2	2
145	Sangeetha	33	149092	2	1	3	2	1	2	2	2	0	0	1
146	Kamala	35	149097	2	2	1	1	2	3	2	0	0	0	0
147	Kala	27	149116	1	2	1	2	2	1	2	0	2	2	1
148	Nisha	40	149122	2	1	1	1	2	3	2	0	0	0	0
149	Durgadevi	36	149134	2	1	1	2	2	1	2	0	3	2	1

150	Vasanthi	34	149143	1	1	1	2	2	1	2	0	1	1	1
151	Bhuvana	30	149149	2	2	1	2	2	1	2	0	3	2	2
152	Radhiga	29	149153	2	2	2	1	2	2	2	0	0	0	0
153	Angayarkanni	27	149167	2	1	2	1	2	1	1	0	2	2	2
154	Rameshwari	43	149174	2	1	1	2	2	1	2	0	1	2	1
155	Kanmani	35	149182	1	1	1	1	2	2	1	0	0	2	1
156	Suseela	40	149191	2	1	1	2	2	1	2	0	3	2	2
157	Punitha	44	148199	2	2	1	1	2	3	2	0	0	0	0
158	Deeparani	31	149205	2	2	1	2	2	1	2	0	1	2	1
159	Malar	29	149216	2	2	2	1	2	3	1	0	0	2	1
160	Jothi	25	149229	1	1	3	2	1	1	2	1	2	2	3
161	Saritha	28	149236	2	1	1	1	2	2	2	0	0	0	0
162	Chellam	28	149237	2	1	1	2	2	1	2	0	3	2	1
163	Baby	35	149248	1	1	2	1	2	1	1	0	2	2	1
164	Renuka	30	149251	2	2	1	2	2	1	2	0	2	2	2
165	Chinnamani	30	149269	1	2	3	2	1	3	2	1	0	0	2
166	Santha	39	149273	1	2	2	1	2	3	1	0	0	2	1
167	Gowri	37	149285	2	1	1	2	2	1	2	0	3	2	2
168	Radha	25	149290	2	2	2	1	2	2	2	0	0	0	0

169	Anusiya	31	149297	2	2	2	1	2	3	2	0	0	0	0
170	Deepika	20	149301	2	1	1	2	2	1	2	0	1	1	1
171	Thavaselvi	35	149309	2	1	1	2	2	1	2	0	2	2	1
172	Deepa	32	149317	1	1	2	1	2	1	1	0	1	2	2
173	Hema	32	149327	2	2	2	1	2	3	2	0	0	0	0
174	Ramya	27	149329	2	1	1	2	2	1	2	0	3	1	1
175	Divya	35	149333	1	2	1	2	2	1	2	0	2	2	1
176	Deivanai	27	149348	1	1	1	1	2	2	1	0	0	1	4
177	Sasikala	33	149351	2	2	1	1	2	2	2	0	0	0	0
178	Selvambal	38	149368	2	1	1	2	2	1	2	0	3	2	1
179	Pattu	36	149372	2	1	1	2	2	1	2	0	3	2	2
180	Paapathy	37	149382	2	2	1	1	2	3	2	0	0	0	0
181	Rogini	30	149399	1	1	1	2	2	1	2	0	1	2	1
182	Gomathy	28	149404	2	2	2	1	2	3	2	0	0	0	0
183	Rasathi	24	149411	2	1	1	1	2	1	1	0	1	2	2
184	Thilagavathy	29	149426	1	2	3	2	2	1	2	0	2	2	1
185	Janaki	23	149438	2	1	1	2	2	1	2	0	3	2	1
186	Parvathy	26	149447	2	2	1	1	2	3	2	0	0	0	0
187	Sumathy	34	149458	1	2	2	1	2	3	1	0	0	2	1



188	Isaiyasari	37	149457	2	1	1	2	2	1	2	0	1	2	1
189	Tamilselvi	24	149469	1	2	3	2	2	1	2	0	2	2	2
190	Mohana	27	149471	2	2	1	1	2	2	2	0	0	0	0
191	Parimala	34	149483	2	1	1	2	2	1	2	0	2	2	2
192	Kalaiyarasi	25	149496	2	2	1	1	2	3	2	0	0	0	0
193	Rekha	27	149507	1	1	3	2	1	1	2	2	3	2	1
194	Pottamal	28	149511	1	2	1	2	2	1	2	0	2	2	1
195	Saradhambal	37	149527	2	2	2	1	2	3	2	0	0	0	0
196	Kannagi	35	149538	1	2	2	1	2	3	1	0	0	1	3
197	Jeyanthi	35	149549	2	1	1	2	2	1	2	0	3	2	1
198	Paapa	30	149558	2	2	1	2	2	1	2	0	3	2	1
199	Jenmaragini	27	149560	2	2	1	1	2	3	2	0	0	0	0
200	Malliga	29	149579	2	2	1	1	2	3	2	0	0	0	0